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METHADONE TREATMENT AND DRUG ADDICTION

HEARING

BEFORE THE

SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

MARCH 23, 1990

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CONTENTS

Page

Opening statement of:

Hon. Charles B. Rangel 1
Hon. F. James Sensenbrenner, Jr 2
Hon. James H. Scheuer 3
Hon. Edolphus "Ed" Towns 4
Hon. Benjamin A. Gilman 4
Hon. Christopher Shays 5

Testimony of:

Arthur Webb, director, N.Y. State Division of Substance Abuse Services.... 5
Mark V. Nadel, Associate Director, National and Public Health Issues, U.S. General Accounting Office 7
Gene R. Haislip, Deputy Assistant Administrator, Office of Diversion Control, U.S. Drug Enforcement Administration 10
George E. Woody, M.D., chief, Substance Abuse Treatment Unit, Philadelphia Veterans Affairs Medical Center 29
Mark Parrino, administrative director, Gramercy Park Medical Group and President, Northeast Regional Methadone Treatment Coalition, Inc 34
Robert Newman, M.D., president, Beth Israel Medical Center 38
Bertram John, Ph.D., program psychologist, St. Mary's Hospital of Brooklyn Addiction Service Department 40
Dr. Drew 44
Charles R. Schuster, Ph.D., Director, National Institute on Drug Abuse, U.S. Department of Health and Human Services 63
Stuart L. Nightingale, M.D., Associate Commissioner for Health Affairs, Food and Drug Administration, U.S. Department of Health and Human Services 66

Prepared statement of:

Hon. Charles B. Rangel 89
Arthur Y. Webb 93
Mark V. Nadel 103
Gene R. Haislip 113
George E. Woody, M.D 118
Mark W. Parrino 216
John C. Ball 224
Robert G. Newman, M.D 237
Charles R. Schuster, Ph.D 312
Stuart L. Nightingale, M.D 321

METHADONE TREATMENT AND DRUG ADDICTION

FRIDAY, MARCH 23, 1990

House of Representatives,
Select Committee on Narcotics Abuse and Control,
Washington, DC.

The committee met, pursuant to notice, at 9:45 a.m., in the Ceremonial Courtroom, U.S. Court of International Trade, New York, NY, Hon. Charles B. Rangel presiding.

Members present: Representatives Charles B. Rangel; James H. Scheuer; Edolphus "Ed" Towns; Nita M. Lowey; Lawrence Coughlin; Benjamin A. Gilman; F. James Sensenbrenner, Jr.; Christopher Shays; and Charles E. Schumer.

Staff present: Edward H. Jurith, staff director, George R. Gilbert, counsel, Nancy Hobbs, minority staff director, and Richard Baum, minority professional staff.

OPENING STATEMENT OF CHARLES B. RANGEL, CHAIRMAN

Chairman Rangel. The Select Committee on Narcotics will now come to order. Jim Scheuer, one of the senior, more dedicated members of the Select Committee is once again with us. Jim Sensenbrenner, is acting minority ranking member until such time as Larry Coughlin gets here. Today we will be concentrating on methadone programs and diversion.

I want to make it abundantly clear that this committee's inquiry is not meant to damage the prestige and credibility of methadone programs that provide rehabilitation services, counseling and are anxious to return someone to society better than when they went into these centers. What we are concerned about—and we will hear the results of investigations by our State Agency, by the Drug Enforcement Administration, and by the Food and Drug Administration—are people who are abusing the system, running so-call methadone treatment systems but not providing any supportive services, the result being that many case workers have to handle 30, 40, or 50 patients. In some of these centers, the patients are still taking drugs, in other centers the patients are knowingly selling the methadone outside of these clinics in order to obtain cocaine and heroin.

There are some that believe that we should get involved in reviewing the legalization of drugs, and I would say to those people that they ought to take a hard look at some of these State and federally subsidized programs. They would soon see that we are, indeed, involved in legalized drugs. I'm here to state, without fear of contradiction, that within my congressional district we have crooked doctors and pharmacists, who are reimbursed by the Federal, State and city governments, who have opened up so-called clinics for the sole purpose of overprescribing legal drugs. They have given to these patients supportive hose, heating pads, prepackaged mind altering drugs, without examination or without any care at all for any standards that involved medical treatment. They've been operating for years in our communities and while some have been closed as a result of State action, again we see a failure on the part of the Federal Government to set up any type of standards for these people to operate in the poorest of the poor communities with the most helpless constituency and that is the drug addict.

So, today, we will hear testimony about people that are, indeed, dying as a result of drug overdose, and about emergency wards taking in patients that have taken too much of one drug or the other and in most of the cases, the other drug is methadone.

I conclude my opening statement by saying that clinics that provide vocational and educational services, counseling services, and are indeed concerned more about getting people back into a productive life, are the type of programs that we are supporting. To those people who are anxious to talk about no frills, no services, and merely the dispensation of methadone, I'm suggesting to you that it is very dangerous and certainly has proven to be life-threatening.

I'm looking forward to the testimony today of the New York State Division of Substance Abuse services which has done an outstanding job in oversight; the Drug Enforcement Administration; and, of course, the General Accounting Office, that in a by-partisan way has always been there to assist the Congress, not only in support of legislation that we're considering, but in oversight, which is just as important. We look forward to listening to the providers of services, of methadone services, in the metropolitan area as well as Philadelphia, and of course the last panel, I hope will listen carefully to the abuses, so that they will be able to share with us their recommendations to see that at our next hearing we will not have the problems that we face today.

[The statement of Congressman Rangel appears on p. 89.]

The CHAIRMAN. The Chair now recognizes Jim Sensenbrenner.

STATEMENT OF HON. F. JAMES SENSENBRENNER, JR.,

Congressman SENSENBRENNER. Thank you very much, Mr. Chairman, and it is a pleasure being here today to provide a perspective from outside the New York delegation on this very important issue. I am delighted that we could come to New York to examine the critical and controversial issues before us today. Let me add, that it is a great honor for me to serve on this committee with you. While we may disagree on some issues, no one can question the important leadership Charlie Rangel had demonstrated in our Nation's struggle against drugs.

One of the most critical aspects of President Bush's national drug control strategy was to pledge not only to focus on expanding treatment capacity, but also to attempt to enhance quality and accountability, and that's what we're here today to look into.

Yes, we do need more treatment slots, but we need treatment slots that are effective in helping drug addicts become drug free. I think there's general agreement among all in this field, that methadone treatments without a bridge to more effective treatments for a permanent weaning from heroin dependency is not a good policy.

But I'm concerned about the viability of minimum maintenance treatment. Before we go ahead with the national expansion of this type of methadone treatment, we had better make sure that strong evidence suggests it works and evidence that demonstrates it is an effective bridge from heroin addiction to being drug free. I hope to hear the results of public hearings or the current status of rule making within the executive branch of government during this hearing.

Indeed, we are here to review all sides of this issue and I look forward to a good discussion.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. We've been joined by Congressman Ed Towns, a dedicated public servant who has been involved in the struggle against drug abuse long before he joined us in the Congress. We welcome you to the hearing.

Mr. Scheuer, do you have an opening statement?

STATEMENT OF HON. JAMES H. SCHEUER

Congressman SCHEUER. Well, very briefly, Mr. Chairman, I want to congratulate you for having organized this hearing for the purpose of scrutinizing how we can do a better job of treatment. For too long we have had a predilection to concentrate on drug interdiction as the answer. More law enforcement on the poppy fields of whatever country—grower adaptation. Then finally, end the drugs at the borders, we're spending twice as much on law enforcement to prevent drugs from coming into our country and into our neighborhood than we are with treatment, rehabilitation and education combined. That has proved to be a totally failing posture. Drugs are plentiful in this country. In the 15 years that I've been on this committee, since it's very inception, there has never been a time when the protectors of the Drug Enforcement Administration and the preceding agency, the Federal Bureau of Narcotics and Dangerous Drugs, there has never been spreading of any of those top officials have told us that we've picked up even as much as 5 or 10 percent of the drugs that are coming into this country. That means that as drugs seizures increase and confiscations of drugs in automobiles and ships and airplanes continue, and as arrests continue to soar, we don't see, on the other side of the spectrum, a reduction in drugs coming into the neighborhood, we see a concomitant increase. Increase of arrests and seizures of all kinds, and increase of drugs coming into the neighborhood. That simply means that the drug overlords are looking at the seizures and the loss of boats and ships and airplanes, as a cost of doing business. Mr. Chairman, they dump that much into the——

The CHAIRMAN. Sir, we would like to concentrate on treatment of methadone treatment.

Congressman SCHEUER. We had excellent testimony recently, from the National Association of State Alcohol and Drug Abuse Directors. They say the treatment works. They tell us that society saves about $11.50 for every $1 that we invest in treatment. We're not providing enough of it. Only one child—addicted child—out of 13 that needs treatment, is getting it. We have to have treatment on demand for every drug addict in this country. We have to have comprehensive treatment that just doesn't, just doesn't address itself alone to the particular addiction, but addresses itself to the total complex of reasons why that individual is an addict in the first place.

I can't think of a more important program for addressing the problems of drug addiction 5, 10, 15 years from now, than to make sure that every kid who is at education risk in our school system, every 3 year old, 4 year old, and 5 year old, has an enriched preschool experience. If we invest money in Head-Start, we're investing money to reduce the drug problem in our country 5, 10 years down the road. This is an excellent hearing you've designed but, how do we get treatment to every person in the country that needs it? How do we get comprehensively designed, thoughtful, integrated treatment to all those human beings with some form of addiction? I congratulate you on this hearing, Mr. Chairman.

The CHAIRMAN. The Chair wants to recognize any member that wants to address the question of treatment and, more specifically, methadone treatment.

Mr. Towns.

STATEMENT OF HON. EDOLPHUS "ED" TOWNS

Congressman TOWNS. Thank you very much Mr. Chairman. I would like to first begin by commending you on the outstanding job that you've done in terms of providing leadership for this committee. I think that the treatment of this issue has been extremely well coordinated. It must also be comprehensive. I am hoping today, witnesses will recommend new approaches to us as Members of the Congress. The question should be, if you were in my position, what would you do? I'm anxious and eager to hear what our witnesses have to say.

The CHAIRMAN. The Chair would like to recognize the presence of Federal Judge James Watson. It's indeed an honor that we are able to use this building and more of an honor that he would grace us with his presence. Thank you so much, Judge.

Mr. Gilman, my partner and long time friend.

STATEMENT OF HON. BENJAMIN A. GILMAN

Congressman GILMAN. Thank you, Mr. Chairman. Again I want to thank you for arranging a very relevant hearing as we examine better ways to provide rehabilitation to those children who are impacted by drug abuse and substance abuse. There is too little oversight on any of our programs and of this one particularly. The GAO report which just came out, points out some very serious shortcomings in our methadone treatment centers and the methods that they are using and the way they are making certain that the methadone is being properly administered. So I welcome the kind of expert testimony that's before us today, to help us determine just how far we should be going with methadone treatment, what we can do to beef it up if that be the course, or whether we should be pursuing some other course.

We all recognize that there is no black and white in treatment and rehabilitation. Everyone has a different version, a different kind of theory on how best to treat and rehabilitate.

We're all exploring the best way to rehabilitate and treat the poor victims of drug abuse. God knows we have too many addicts out there today who are impacted with substance abuse. As we try to eliminate the supply side we also have to make certain we are doing enough on the demand side.

So again, I thank you, Mr. Chairman, for bringing us together on this important hearing.

The CHAIRMAN. The Chair welcomes Mr. Shays one of the newer members of the committee and of the Congress, but certainly one who has demonstrated enormous energy in the struggle against drug abuse, and we're glad that you were able to come to us from Connecticut for this hearing.

STATEMENT OF HON. CHRISTOPHER SHAYS

Congressman SHAYS. Thank you, Mr. Chairman. I just want to thank you for conducting these hearings and to be on record as saying there is no one solution to containing the drug problem, we've got to do all of the above, and methadone clearly has a role to play. My general conclusion is that if the Yukon Huskies could win a basketball game with one second left, anything is possible. [Laughter.]

The CHAIRMAN. For our first panel of witnesses we have Arthur Webb, who is our new Director of the New York State Division of Substance Abuse Services, who brings with him a wealth of experience; Mark Nadel, Associate Director for National and Public Health Issues at the U.S. General Accounting Office and he will be accompanied by Walter Raheb, and again I congratulate the GAO for a great job.

And Gene Haislip, an old friend from the Drug Enforcement Administration who will also be revealing a report, so this morning, we'll hear the results of three investigations into abuses in this area. One from the State, one from the General Accounting Office and one from the Drug Enforcement Administration. We will start with Mr. Webb.

STATEMENTS OF ARTHUR WEBB, DIRECTOR, N.Y. STATE DIVISION OF SUBSTANCE ABUSE SERVICES; MARK V. NADEL, ASSOCIATE DIRECTOR, NATIONAL AND PUBLIC HEALTH ISSUES, U.S. GENERAL ACCOUNTING OFFICE; WALTER RAHEB, U.S. GENERAL ACCOUNTING OFFICE; GENE R. HAISLIP, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, U.S. DRUG ENFORCEMENT ADMINISTRATION

Mr. WEBB. Thank you very much, Mr. Rangel. I'm Arthur Webb, and members of the committee, it's a pleasure to be here. I've been on the job for 6 weeks now, so I guess that makes me an expert. I was appointed by Governor Cuomo on February 13, and confirmed.

[The statement of Mr. Webb appears on p. 93.]

I'm Arthur Webb, the new Director, OK.

The CHAIRMAN. Well, you're still Arthur Webb.

Mr. WEBB. I'm still Arthur Webb. [Laughter.]

The CHAIRMAN. Well, I hope you don't mind if we take the testimony, if the members have no problem in hearing, I think we'll move forward with the testimony and I hope that the press would refrain from participating at the hearings. [Laughter.]

Mr. WEBB. I'll just speak loud enough, Mr. Chairman.

The CHAIRMAN. Bob, is the gentleman there a part of the Federal building? OK, great. Would you tell the other gentleman to refrain from? I mean there's a limitation to freedom of the press. [Laughter.]

Mr. SHAYS. This is the first time I've seen you lose control of a committee. [Laughter.]

The CHAIRMAN. Welcome to New York. [Laughter.]

Mr. WEBB. We'll give it one more try. I'll speak loud enough, I've never needed a mic before. Mr. Rangel, members of your committee, I've been on the job for 6 weeks and what I have found in the last 6 weeks really deeply distresses me and concerns me. We have a program that's been in existence for about 20 years, serving 35,000 individuals and I believe it needs a major overhaul. In fact, I've called upon the provider system to work with me, starting immediately, to upgrade the quality of care and services, to expand the comprehensive approach to individuals who need more than just methadone, and to develop a 5 year plan. Governor Cuomo appointed me to take over the drug abuse services in New York State, and he is calling for one of the most aggressive expansion of treatment services in the country. We're going to bring on close to 10,000 new treatment beds, we're trying to expand by 20,000 ambulatory care slots in the State of New York, but we are going to do it, though, in the most cost effective, and the best way we can to upgrade the quality care.

First, a couple of things. First of all, 35,000 individuals, I have a pragmatic problem. These individuals, first of all, have sought treatment and we shouldn't castigate all because of the few that divert and loiter. We should not castigate all those who are trying to achieve and make a change in their lives.

My job, now, is for 35,000 individuals, what do I do? With HIV positive on the increase, the continuing use of alcohol, the continuing use of drugs, unemployment and related health-care problems, now what do I do? Methadone is effective. Heroin's on the increase. We need to serve many more people. We have many more people who are addicts out on the streets, than the 35,000 methadone treatment programs could ever reach. The question, I share with you, the quality of care, the diversion, the public glare and scrutiny that's going on deserves immediate attention. When I started, I conducted six unannounced visits to begin a new effort. We've totally reformed our quality assurance team in the last 6 weeks, we're going to continue to do unannounced visits. We put a new team in quality care, we've upgraded the standards, we're not for the expansion of interim maintenance clinics, and what we're really trying to see here is what we can do to improve the quality of care.

Keep in mind, we spend about a $100 million on methadone maintenance in the State of New York. Ninety percent of it are

State and local funds, only $10 million of that are Federal funds. It is a State program; I license, I regulate, and I fund. We only spend on the average of $3,500 per person, per year in methadone maintenance. Now, tell me, what can you do with $3,500, other than to devise some kind of safe, secure method of distribution, and even that is called into question.

So, what I am calling for in this 5 year plan, is a major change in the way we deliver health care. Keep in mind, again, a person is seeking care, trying to get their addiction under control, is this the gateway, is this the entry-point, maybe it is. Maybe we can use this as a method to get people into other kinds of services that they need, and we believe certainly they at least deserve.

So, the increase calls for treatment expansion by Governor Cuomo, increased quality care, calling for a major overhaul, I share with you the deep concern that you had and your members have, about what is going on with these clinics.

The last thing I would like to call upon is the Federal Government. What is the Federal Government doing, what can it do, and where should we go. Several things: one, I appreciate the GAO study and the DEA effort, however, we need a lot more cooperation and collaboration. We don't need separate entities running around the country trying to do one-ups-manship. What we need is cooperation with the DEA, the GAO, et cetera. The second thing, if we're that concerned about it, where are the Federal dollars to help me evaluate this program? Because I'm going to be calling upon the Federal Government for a major evaluation study that will allow me to expedite the effort to improve the quality of care and cost effectiveness.

If we're really concerned about getting people off methadone, where are the Federal funds to help us move from methadone to abstinence? We need to establish and expand demonstration programs We don't need any more new standards, we just need to make sure that the standards are in place, which are very tight, and methadone is probably one of the most highly regulated controlled substances in the country, we need to make sure we can enforce it and we have the dollars to be able to improve the quality of care. That's my simple message to you, thank you very much.

The CHAIRMAN. If there's no objection, we'll hear from the entire panel before the members can inquire.

Now let's hear from the GAO, Mark Nadel, accompanied by Walter Raheb.

STATEMENT OF MR. NADEL

Mr. NADEL. Mr. Chairman, and members of the committee, I'm pleased to be here today to discuss our report on methadone maintenance treatment programs, which you requested.

[The statement of Mr. Nadel appears on p. 103.]

Mr. NADEL. In response to your request, we reviewed the activities of 24 methadone maintenance treatment programs in eight States; California, Florida, Illinois, Maryland, New Jersey, New York, Texas, and Washington State. We also assessed the potential effectiveness of the proposed interim maintenance program, as you also requested.

In summary, we found first, many programs were not effectively treating heroin addiction. A substantial percentage of their patients continued to use heroin after six months of treatment, and other drugs were also used, primarily cocaine. Second, treatment programs set their own goals, policies, and practices, which varied widely. However, programs did not evaluate the effectiveness of their treatment and, therefore, did not know the extent to which those goals were being met. Third, just as program goals varied, we found great variation in the services they provided, staffing levels and after care. Fourth, there are no Federal performance standards and Federal oversight of methadone programs has been virtually nonexistent. Finally, recent Federally sponsored research found that interim maintenance would not significantly reduce IV heroin use and the corresponding risk of AIDS. GAO also did not find clear evidence of a serious overall shortage of treatment slots that would justify interim maintenance.

I will turn briefly now, to some background on the program, before going into each of these points into more detail. There is no typical methadone maintenance treatment program. Programs can be found in rural, suburban as well as the inner city areas. They range in size from less than 100 patients to over 700 patients. While most programs are established by not-for-profit organizations, there are also private clinics and public programs. Many private programs do not receive public funding, and charge their patients a fee for services. Publicly operated and nonprofit programs may receive public funds. These funds may be in the form of Medicaid, block grants, or other State or local government assistance.

The Food and Drug Administration, the New York Institute on Drug Abuse, NIDA, and the Drug Enforcement Administration, DEA, share responsibility for regulating methadone maintenance treatment.

I will turn now to program treatment goals, policies and results. Methadone treatment programs establish their own goals, policies, and practices, and these goals varied widely. The goals vary from treating only heroin addiction, to treating abuses of all drugs with the eventual goal of getting the patient free of all drugs, including methadone.

A wide variety also existed among program policies, with respect to methadone dosage levels, urine testing, dismissal of patients, and counselor staffing levels. An adequate dose of methadone is necessary to stop heroin use. According to NIDA, 60 milligrams is generally the lowest effective dose, and low dose maintenance, 20 to 40 milligrams, is considered inappropriate. The average dose of methadone at 21 of the 24 clinics we visited, however, was less than 60 milligrams.

Methadone maintenance can be an effective treatment for heroin addiction, but judging from the continued use of heroin among patients, in practice nearly half the programs we visited are not effective in treating heroin addiction.

At 10 of the 24 programs, more than 20 percent of the patients continued to use heroin after 6 months of treatment. This is a higher percentage than experts believe should occur among patients and treatment.

At the 24 programs we visited, urine testing to determine the use of illicit drugs ranged from once a week to eight times a year. At the five New York programs, testing occurred once a week, but only one of the five programs observed sample collection in order to prevent patient tampering with the sample. A consequence of continued heroin use or other drug use could be dismissal from a program. Fifteen of the programs dismissed patients for repeated drug use, while nine did not.

Comprehensive services including counseling and vocational training have been found to be essential to program effectiveness. Here, too, we found wide variation. Counseling is a key component of treatment. Many counselors and program directors told us it was difficult to provide more than minimal counseling to patients when a counselors caseload exceeded 35 patients. Ratios of counselors to patients, we found, ranged from between 1 to 15, to 1 to 96.

Research indicates that a good relationship between a counselor and a patient, which is developed over time, improved treatment outcomes. The average length of employment for counselors at the 20 programs that provided us with data ranged from 6 months to over 8 years.

[Pause.]

Most of the programs were lax in providing vocational and educational services, which are required by Federal regulation. Few programs had such services on their premises and those that referred patients to services off-sight did not track patient use or progress.

Finally, none of the methadone maintenance programs we visited, evaluated the effectiveness of their treatment.

I'll turn now to the question of Federal oversight. Federal regulations require that in order to use methadone in treatment, programs meet certain conditions, such as requiring urine testing for continued drug use. FDA and NIDA have primary responsibility for regulating programs. But these agencies provided virtually no oversight of the programs between 1982 and early 1989. But when FDA did begin inspecting for compliance, with the administrative requirements of Federal regulations, it did find serious problems. FDA inspections in fiscal year 1989 found 52 programs that failed to first, meet minimum urine testing requirements, standard for admissions and medical evaluation requirements; second, comply with frequency of attendance or take-home requirements; third, maintain an adequate patient record system; or fourth, meet other minimum program standards. Three of these 62 programs were in New York.

Current regulations, I should note, are process rather than results oriented. There are no Federal treatment performance standards for methadone maintenance treatment programs such as the overall level, if any, of continued drug use that is permissible. Thus, oversight has been oriented toward regulatory compliance rather than program effectiveness.

In March 1989, FDA and NIDA proposed revised methadone maintenance regulations to allow interim maintenance. The provision of methadone without any counseling or rehabilitative services. The purpose is to get addicts who are waiting for comprehensive treatment to reduce IV heroin use, with its attendant risk of AIDS.

The proposal is based on the assumption that many addicts are on a waiting list for treatment and that interim maintenance would result in reduced IV heroin use and the risk of AIDS. Both assumptions, however, are questionable. First we find that while some programs did have waiting lists, there is no clear evidence of an overall serious shortage of methadone treatment slots.

Second, a recent study by the Department of Veterans Affairs and University of Pennsylvania researchers, found that interim maintenance is not effective in reducing IV heroin use. The researchers stated: "Methadone by itself, does not guarantee clinical improvements or reduce AIDS risk." That was a quote from the study.

The report concluded that merely increasing the availability of methadone in the absence of administrative, counseling, and rehabilitative services may not adequately protect the majority of patients from continued drug use and the risk of AIDS.

In our report we have made a number of recommendations to the Secretary of Health and Human Services. These include the development of performance standards, guidance for data collection on program performance, and increased program oversight. Additionally, we recommend that the interim maintenance program be withdrawn until there is sufficient evidence to clearly demonstrate its effectiveness in actually reducing intravenous heroin use.

This concludes our prepared statement, Mr. Chairman, and we'd be pleased to answer any questions you may have.

The CHAIRMAN. Thank you Mr. Nadel, and at some point I'd like to question Mr. Raheb, too.

Mister Haislip, I've been with you as you tracked down drug pushers, the French Connection, the Golden Triangle, Mexico, Central America, South America and now you're adding battle stars as doctors are pushing drugs. We welcome your testimony.

STATEMENT OF MR. HAISLIP

Mr. HAISLIP. Thank you and good morning Mr. Chairman and distinguished members of this committee. I am pleased to be before you again because I consider that we have an important and historical partnership in trying to deal with the many difficult drug problems that beset our Nation, and I'm here this morning to talk about one of those which I think merits more concern by all of us than it has previously received.

Last year we became concerned at the Drug Enforcement Administration with the increased, what seemed to us increasing reports, of the diversion and availability of methadone. Since virtually all of the methadone manufacturing in this country is for narcotic addiction treatment programs, we presume that such diversion as exists, would largely come from those sources. For that reason we undertook a very limited intelligence probe in the New York area to test this hypothesis. When I was previously before the committee in August 1989, we reported on the results of that intelligence probe, which disclosed to us that methadone was readily available in the illicit traffic in the neighborhood of a number of treatment programs which were operating in this area.

As a consequence of those findings, and as a follow-up measure, we undertook then to investigate several programs which were targeted on the basis of the availability of the illicit distribution of methadone in the neighborhood. As a consequence, yesterday, I took certain actions on the part of the Drug Enforcement Administration against two programs and I would like to explain what that means and why we have done it. I have submitted a statement for the record. I would like to briefly summarize the salient points of that statement.

[The statement of Mr. Gene R. Haislip appears on p. 113.]

Mr. HAISLIP. I think it's always necessary to begin by reminding everyone that methadone is a schedule two narcotic, which means that it is in the highest classification of legal control for any drug which has a legitimate use. It does have a legitimate use, it is, nevertheless, a very potent and addicting narcotic drug which has a value in the illicit traffic, and always has had such value since it has been available in our country. In addition to this illicit traffic, however, methadone appears to be useful as an adjunct in the treatment of heroin addiction when it is accompanied with the other essential program elements.

Well, my experience is that this is a very demanding endeavor, both because of the nature of this drug and because of the history of the patients involved in these programs. It requires extremely rigorous security and a great deal of discipline in dealing with the patients and with the entire treatment circumstance. Perhaps because it has such demanding requirements, I'm afraid that what has occurred here is that in many cases that high standard necessary to ensure that this drug is used with some beneficial effect is often not met by many programs. This is, perhaps, due to the difficulties in management, perhaps it is due in part to disregard for statutory and regulatory standards, and maybe in some cases even represents a philosophy contrary to that of the rest of society.

But we have found, as a bottom line is, that as a consequence of the laxity in certain programs, that the neighborhoods in and around these programs are daily scenes of illicit distribution of methadone. It is a common and daily occurrence. I think we have to insist that the programs that are operated in such a manner as to supply this narcotic drug, take responsibility for what happens in their neighborhoods and for what happens to this narcotic and addicting medication.

Based on the findings from the program that we had begun last year, we therefore targeted five specific programs for a greater in-depth investigation, not just with reference to what was transpiring in their neighborhoods, but with regard to their practices under the law and regulations that are prescribed for their conduct. We thought it would be most useful to undertake these investigations in partnership with the Food and Drug Administration and the New York state Bureau of Controlled Substances, and for that reason, this was, in fact, a tripartite investigation utilizing the investigative personnel of all three of those agencies.

As a consequence of those findings we have taken a certain action in two cases which I will describe. We took this action because of findings that a great many of the patients, in accordance with the urine testing that had been conducted, were in fact abusing other illicit drugs, most especially cocaine, which was found to be involved in almost half of the patients, as well as prescription drugs, other narcotics and so forth. We found, also, that there was a lack of discipline in curtailing take home privileges or in follow up as a result of the findings from urine testing. We found important record keeping failures, security failures; we also found that some records appeared to have been back-dated and altered in ways that were confusing if not suspicious. The bottom line to our findings was that these two programs were being operated in such a way that they could, and should, be held responsible for having created the situation that was prevailing with regard to the sale of medication that they had dispensed into the illicit drug traffic.

I would like to emphasize that this is not, and should not, be taken as an indictment, necessarily, of all of the personnel associated with those two programs, some of whom, no doubt, are very hard-working and dedicated individuals. Nor, certainly, of all the patients who might be associated with those programs. But the fact is that the operation of these programs in our opinion, had become part of the problem and not the solution. Their operation, based on this history, is no longer in the public interest as we understand and apply the statutes that the Congress has given us to enforce. Therefore, yesterday, we served upon these two programs an order to Show Cause why their DEA registration should not be terminated. I would like to explain just what this means. This action serves notice of our findings and our concerns, and the basis for it. It advises them of their right to request an administrative hearing to present evidence to contest these findings if they so desire or to submit evidence without a hearing.

At the conclusion of this process, and they have 30 days to take to make notice under this letter, at the conclusion of this process, depending upon the findings of an administrative hearing or the further review of this evidence, their DEA registration number may be revoked. This would mean that they would no longer be entitled under the law to order or dispense or prescribe these narcotic medications. This is a drastic action. We have only taken it because of the egregious circumstances presented; we regret having to do so, but we are faced with no other operative alternative.

Moreover, I must confess to you that it is apparent to us from the accumulating evidence that we have heard here this morning and in the previous hearing, which you held on the subject, as well as the intelligence that we are receiving, that this undoubtedly needs to be done in a great many more circumstances which we have not, thus far, been able to address.

I hope this explains the action that we have taken. I also hope it underscores the position that we have, which is that the dispensing of narcotic drugs to addicts, without the rigorous requirements of a bonafide treatment program and the controls which society has a right to expect, since society, in one way or another, support these programs, is not a solution to the problem, it is a part of the problem. It actually results in augmenting and supporting those additional supplies of narcotic drugs and other drugs of abuse in the illicit traffic which are made available by the more conventional means of illegal distribution of drugs in the illicit traffic.

Thank you Mr Chairman and members, that concludes the summary of my remarks. I'd be pleased to answer such questions as you may have.

The CHAIRMAN. Well, I'm pleased that we're joined by Larry Coughlin, my friend and the ranking minority member of this committee. Would you care to make any statement at this time?

Congressman COUGHLIN. I think that Mr. Sensenbrenner has made my opening statement, I'm sorry that Amtrak was not on time today [laughter]. So I'm glad to be here and evaluating these hearings.

The CHAIRMAN. Thank you for making the effort. I want to welcome, not a member of this committee, but certainly an outstanding Member of the U.S. Congress, who all of you know, Chuck Schumer. Thank you for joining with us.

This panel has given some pretty powerful testimony this morning. And I think we all want to underscore that we are here to support programs that include the use of methadone, that have the supportive services and the goal and objective to rehabilitate human beings who are addicted to heroin. I guess because of what we're dealing with, all of us will have to say that from time to time, for fear that good programs appear to be hit with the same brush as these bad programs are. While it seems to me that like the distribution of these drugs have taken place without adequate supervision for decades, I would not get involved too much in that because right now I think that there is an explosion of recognition that we need more treatment and more services for the growing number of addicts that are on line.

So, perhaps this is the best time to focus as we talk about treatment on demand, are we talking about legal drug pushers getting involved, under the cloak of treatment being subsidized by city, State, and Federal Government? Now, I would just like to ask, in the course of the multiagency investigation that has taken place, was there ever any reason that doctors knew or should have known of the lack of accountability at the centers and the diversion of methadone that was taking place outside of the centers.

Let me start with the General Accounting Office.

Mr. NADEL. Thank you, Mr. Chairman. I think I'll let Mr. Raheb, who is more intimately involved in that aspect of it.

Mr. RAHEB. Yes, certainly. When we spoke with the doctors trying to get a sense of what was going on at the programs, they were focussing on their patients and many of the programs, the physicians were not there full time. Such that the patients received their doses at the dosing station from either a registered nurse or an LVN, Licensed Vocational Nurse. I don't think our study went to the extent of trying to get a sense on was each of the patients being tracked by the person providing the dose. When we spoke with counselors, we got a sense that, in some cases, they were trying to get a good sense on how the patient was doing, what was involved in the treatment and the progress of the patient. In other cases where counselors were so busy they didn't have an opportunity, when you have one counselor to 96 patients they may not have had the opportunity to have focussed on each of the patients to determine progress, such that what was going on outside of the program, what was going on in the community, the counselors, the programs themselves, may not have always had a good sense. So trying to follow the patients wasn't always occurring.

The **CHAIRMAN**. Well, did you get an indication that any of the doctors lived in the community that they were working?

Mr. **RAHEB**. That was not part of our study, so we did not come up with those——

The **CHAIRMAN**. Well, would not the doctors have to go in and outside of these clinics?

Mr. **RAHEB**. That's correct.

The **CHAIRMAN**. Well, weren't the people selling drugs outside of the clinics?

Mr. **RAHEB**. At the programs we visited, we observed that only in one case, but we were focussing more on the patient records and what was going inside the clinic versus outside.

The **CHAIRMAN**. Do you have what the doctor would have, I mean did they just sign the request for methadone?

Mr. **RAHEB**. In many cases the doctor would be involved in adjusting, the doctor was always involved in adjusting increase or decrease in the methadone to the treatment.

The **CHAIRMAN**. Well, should not that doctor have talked with the patient in order to do that?

Mr. **RAHEB**. You would think that should occur, yes.

The **CHAIRMAN**. Would any of the other panel members like to make any contribution to the question of the doctor's responsibility. Mr. Haislip.

Mr. **HAISLIP**. Well, I would like to add to it in this sense, I know from reviewing the files that ah, at least in one of these two cases, if not both, the investigators did ask the personnel of the program if they were aware of what was happening in their neighborhood outside their door, and they were told that, no, they were not aware. This is very difficult to believe or accept, since it can be observed daily, and in fact, many of us saw it on television last night. So, I just cannot understand how they could be so blind as to what is occurring in their community, because in these cases these patients, so-called patients, were selling medication. They did not even go to the trouble to leave the neighborhood, they established their center for distribution right around the corner.

I don't see how week after week and month after month, and year after year, people can be oblivious to what is happening there. Well, whether they are or not, I don't think we can accept that kind of irresponsibility. They should be aware if they are not.

The **CHAIRMAN**. Are the doctors, to your knowledge, reimbursed by the number of so-called patients that they dispense the prescribed methadone for or are they on salary?

Mr. **HAISLIP**. I think this arrangement varies a great deal and we have not focussed on the financial arrangements. It would probably be the case that the GAO might have more information on that than we would.

Mr. **NADEL**. In the clinics we visited, Mr. Chairman, they were all on salary. And as Mr. Raheb pointed out, generally they were not full time.

The CHAIRMAN. The institutions are reimbursed based on the census and the number of patients that they treat?

Mr. NADEL. That's correct.

Mr. WEBB. Mr. Rangel, ah, we use kind of a comprehensive approach to this, which we are going to expand. We have probably one of the more unique street research activities going on, which you know, Mr. Hopkins is internationally renowned, and we have constantly monitored this, in fact, as I moved in to 125th Street, my offices there in your district, I was appalled to see the kind of market outside these places. The loitering and the diversion that was going on, and through our street research efforts we're going to continue to monitor this and with a joint police neighborhood action group when we went out there, we believe we can begin to disperse this activity.

One thing I've also found is that everything has a price in the drug world. When there's a market, they'll be a price, and when there's a market there will be distribution. That's what we need to kind of penetrate on. Not only do we have to improve the quality of care inside the clinics, not only with the doctors and the clinicians and the counselors and the referrals, we have to do it on the street side, too.

The CHAIRMAN. Yes, but Mr. Webb, we're talking about doctors being involved in this and you're talking about supply and demand. I've been through that for 30 years, but we're talking about doctors. Let me just ask this. Are any of you aware that we have doctors and pharmacists setting up shops in our communities for the sole purpose of providing legal drugs, over prescribing them and only dealing with the addict population. Mr. Haislip.

Mr. HAISLIP. Mr. Chairman, thank you for making that point, because that is one of the major assignments that I have in DEA. We are constantly investigating and arresting such doctors and owners and managers of pharmacies who are knowingly engaged in profiteering by supplying drugs which they obtained, legitimately, at very modest prices, into the illicit traffic, at extremely inflated prices. Sometimes inflated by thousands of percent, and that would give me a chance to make another point if I may and that is to say that although many of these legitimate narcotics and stimulants have important medical uses and they do and I always say that, we must not loose sight of the fact that in terms of pharmacology and in terms of their abuse and value in the illicit traffic, they are identical to the so-called purely illicit drugs, such as heroin and I could say cocaine. Of course, while the fact of the matter is that cocaine itself is a legitimate drug, most of what we see in the United States comes from illicit sources, thank you.

The CHAIRMAN. But not at this point. Mr. Haislip, what we are saying is that these doctors who blatantly overprescribe, whose sole purpose it is to deal with this type of population, who are reimbursed solely by city, State and Federal Government, are really no different from any other drug pusher operating on the streets of America today.

Mr. HAISLIP. In my view, in these cases, they are no different, it's just another type of drug peddling.

[Pause.]

Mr. **Haislip**. The problem is that we know only a small percentage of these professionals can create a very great problem because they can distribute enormous quantities of these drugs.

The **Chairman**. I want to reiterate what you've said. We have crooks in the Congress, and they are a small percentage, and we try desperately hard to excise them from our population. We have crooks in the criminal justice system, and we do all that we can to eliminate that to have confidence in the system. I do hope that we might hear from the medical profession today to at least admit, that there are unscrupulous doctors among their number, subsidized by the Federal Government that, as pointed out by Mr. Webb, has provided very few standards for them to operate by. Certainly, very little oversight so that we have crooks and thieves among that profession operating in the poorest communities and then people ask why the community says, "Not in my backyard," when the addicts are attracted by the doctors providing the drugs, the same way they are attracted by drug dealers providing the drug.

Mr. **Haislip**. Mr. Chairman, I think you're right and I'd like to comment further. You know, on occasion, we've also had to arrest some of our own agents who've been involved in the illicit drug traffic. I'm afraid that corruption is a danger everywhere in every profession. I would submit to you, that I think the methadone programs which are really well-run and attempting to provide good treatment should embrace the action that we are taking, because I think their good efforts are embarrassed by this other kind of situation that we find. We must always keep that division in our minds.

The **Chairman**. I couldn't agree with you more. Mr. Sensenbrenner, will you yield to Mr. Gilman who I think asked that——

Congressman **Sensenbrenner**. I already have, privately. [Laughter.]

Congressman **Gilman**. Mr. Haislip, you have expressed concern about the security arrangements. Is security the responsibility of the hospital or of the local police officers? For example, what happens if you were to move them away two blocks from the hospital? Shouldn't this be a local police responsibility, not the hospital responsibility?

Mr. **Haislip**. Well, Congressman, I'd like to reply to that at some length.

First of all, I don't ah, think that we want to scatter the problem, I think we want to eliminate it, this is the thing.

Congressman **Gilman**. Well, I think we're all interested in whose responsibility is it to maintain security in the streets in and around the hospital.

Mr. **Haislip**. It is the responsibility of these treatment centers to ensure that their medications are not diverted into the illicit traffic.

Congressman **Gilman**. Shouldn't it be a police responsibility to make sure there's no loitering near the treatment centers, to make certain there is no diversion out on the streets?

Mr. **Webb**. Mr. Gilman, I think it's at all levels. We've asked every one of our clinics to improve, having security officers in those clinics.

Congressman **Gilman**. All the hospitals should have security forces——

Mr. **Webb**. It's one sided——

Congressman **Gilman** [continuing]. To make their own internal operations secure. But what happens when you get out on the street, is it their responsibility to clear the streets for a 10 block radius?

Mr. **Webb**. In the second part of that, we work cooperatively with our neighborhood precincts to really get at this issue. We've done this up in——

Congressman **Gilman**. Are there police in and around the methadone clinics now, are they stationed there permanently?

Mr. **Webb**. No, not in the clinic level, they're on the street.

Congressman **Gilman**. Have we requested that the police——

Mr. **Webb**. We work cooperatively with every precinct in the city, the city police department has been enormously helpful.

Congressman **Gilman**. I don't think you should be putting the burden on the hospital to police a 10 block radius, or whatever is needed to clear the area around a dispensing clinic.

Now let me get back to——

The **Chairman**. Do I understand the gentleman correctly that you believe the hospital has no responsibility as to what is happening to the drugs that they're dispensing?

Congressman **Gilman**. That's not what I'm saying, you're taking it out of context, Mr. Chairman. I don't know that you have to put the burden on the hospital to secure a three or four block area around the hospital——

The **Chairman**. One of the hospitals will be testifying today, and I would like to see what request the hospital has made to——

Congressman **Gilman**. Fine, the agencies, too, should put some criteria out there for local police. Speaking of criteria, Mr. Haislip, have you developed criteria for methadone clinics. I know only at GAO and some of the other agencies indicate that we don't have adequate criteria or adequate arrangement standards set up for these kinds of clinics. I see that you've taken a day before a hearing to put in an order to show cause in one of the hospitals, but I'm curious what we've been doing all these years before this. Why since the 1980's when we started using methadone, or whatever period it was that we started, why hasn't there been a strict, stringent set of criteria put in place with the proper oversight?

Mr. **Haislip**. Congressman, I think that there are criteria and they are reasonably sound. They've been developed over the course of many years, and the Congress also participated in that, as a result of legislation which was proposed by my agency in the early 1970's.

Congressman **Gilman**. Did I hear you say something on the GAO recommendations.

Mr. **Haislip**. The problem I see is that there's been a lack of adequate enforcement and insistence upon adherence to strict standards.

Congressman **Gilman**. Who's responsibility is it in the first place?

Mr. **Haislip**. I think we're all responsible for that, and I have to admit to some responsibility for that as well.

Congressman Gilman. Do you think that you're doing an adequate enough job of oversight?

Mr. Haislip. No; I do not.

Congressman Gilman. Do you think your agency is doing enough?

Mr. Haislip. No; I think we're improving our record, but I think it's only an improvement.

Congressman Gilman. Well, it seems fortuitous for you to suddenly, before the hearing, to visit for the first time a methadone clinic. Have you done that before this?

Mr. Haislip. No, sir; these investigations have been underway for about 4 or 5 months.

Congressman Gilman. Well, I would hope you really improve the oversight and I would hope that there would be a stronger set of standards out there. I note that my colleague has pointed out to me that you started your investigation in September 1988 and went 2 days before the hearing to serve an order to show cause, I would hope there would be much more responsibility in the manner in which we're imposing any kind of regulation on these methadone clinics. Thank you, Mr. Chairman.

The Chairman. Well, I certainly wish the order to show cause had been issued earlier, but I'm certainly not going to be critical because in the view of the Drug Enforcement Administration such violations have existed that this extraordinary measure had to be taken. I'd like to believe, as much as I am critical of the Federal Government of not having sufficient standards nor enforcing them, that doctors do have standards that are outside of the Federal law, as well as the institutions that hire doctors. So, because our law enforcement officials have not been as vigilant as they should have been, I certainly don't think that that takes away from the responsibilities of our doctors and our hospitals.

Mr. Scheuer.

Congressman Scheuer. Thank you, Mr. Chairman. Mr. Haislip, when Congressman Gilman asked you who was responsible, you said we all are. Of all the places where responsibility might rest, where do you think it should rest? If you don't think it should rest with the hospital administrator—certainly not for activities blocks and blocks away from the hospital—should it be in the Health Commissioner of the city, should it be in the law enforcement, should it be the police commissioner, should it be the Department of Health and Human Services, should it be the State Health Commission, or should it be the Congress exercising more continuous oversight over these programs, as funding? Where should the responsibility be for continuous oversight over what seems to have been a problem sort of real life topsy, that anybody is focussing on, focussing in on, with a sense of real responsibility?

Mr. Haislip. I realize the importance of your question. It is very difficult to respond to because this is such a complex activity that it's inevitable that the responsibility has to be shared. I think that law enforcement at the Federal level, the DEA, has responsibility with regard to the areas of diversion. Now our authority there is incomplete, because we do not have the direct authority to control the so-called take-home privileges, the quantity of drug that is allowed to be dispensed. But, inevitably, the health issues and the standards of medical practice are not appropriate for law enforcement, and need to be the responsibility of those agencies at the State, local, and Federal levels, concerned with treatment. Clearly, none of this is likely to be done very often or very well, if the Congress does not take an oversight interest in it as it is. So, although I recognize the danger of what you're saying, that we may all walk away from our responsibility because it is the responsibility of all others. Nevertheless, I see no other alternative, because it is the responsibility of all of us.

Congressman **Scheuer**. Again, that cop-out. If everybody's responsible, than nobody's responsible. The one thing we know is, that responsibility has to be structured and delegated at local levels. To say that everybody's responsible is really not the issue and to leave us in the present state of utter chaos, in terms of identifying responsibility, is unthinkable.

Mr. **Webb**. Mr. Scheuer, as a fellow State official, as you are, in the great State of New York, you are going to probably find this quite surprising, but I believe the New York State Division of Substance Abuse Services, which reports directly to the Governor, is responsible for the oversight and we are going to do it. We are increasing the oversight, we're going to increase the quality of care, we're going to increase the effectiveness of overall methadone services. The Federal Government definitely has a role, because it's a controlled substance. It's got to go beyond that. We need a national review of what those outcome measures should be, what effectiveness should be, but we even have to go beyond that. You can't do the kinds of things we're calling for, for $3,500 a year per person, in these methadone programs. Remember, 90 percent of all funds spent in methadone, are State and local funds, not Federal funds. We have a direct responsibility and we're going to improve this quality.

Congressman **Scheuer**. When you say we, you mean the State?

Mr. **Webb**. State of New York.

Congressman **Scheuer**. Right.

Mr. **Webb**. We.

Congressman **Scheuer**. OK, let me ask Mr. Nadel, you're representing the General Accounting Office, you have responsibility for analyzing problems of control, surveillance, accountability, and so forth. So, forgetting about the fact that you happen to be Federal, and just looking at role as one to appraise and define systems for accountability, where do you think we ought to have responsibility for controlling the abuses that we have discovered?

Mr. **Nadel**. Well, there are two issues, Mr. Scheuer. One is the kind of responsibility, the kind of measures we want to use, and the other specifically, who enforces them. In terms of the kind of measures the discussion before about criteria. We come out very strongly for performance measures, for performance criteria. Our criticism is that in addition to there not being enough Federal oversight, virtually no Federal oversight, until the beginning of 1989, the kind of oversight was what we would call compliance oriented, process-oriented. We think there ought to be more attention to the overall level of drug use that's going on, actual patient outcomes. How many people end up getting jobs, how many people end up going back to school, so on and so forth, and we think that——

Congressman **Scheuer**. Mr. Nadel, if you analyze that and provide a flow of information on that, it's information that this administration does not want to hear. Because they don't want to take a holistic viewpoint on drug addiction. They don't want to look at the need for additional investments in education, and this additional investment, including 31 million Americans into a healthcare system from which they are now excluded. This administration is deaf to those appeals. I think you're right. I think you're going to have a hard time making this national administration sensitive to the issues that you are raising.

If this kind of accountability should be vested at the Federal level, where?

Mr. **Nadel**. I think that we can't say at this time, I wish that I could give you a clear answer. We just did not do the kind of management analysis that will enable me to say, this agency ought to have it. As you say, it is divided. It was not our sense, however, in looking at Federal oversight that the problem was one of divided responsibility. Because it's not really all over the map in the Federal Government, a big chunk of it is within the Department of Health and Human Services, and that's why our recommendations are squarely targeted at the Secretary of Health and Human Services.

Congressman **Scheuer**. Well, I applaud the broad gauge of your vision. If the Federal Government were looking at this thing from a comprehensive point of view as to what really impacts addiction, perhaps they'd do a better job than they're doing, of providing a Head Start enriched preschool experience for only one-sixth of the kids who are in urgent education risk. Now, President Bush proposes to add $500 million, which would take that from 16 percent of the kids or about a one-sixth, to maybe 20 or 21 percent. We will still, after President Bush's budget is passed, be excluding 80 percent of the kids who are in urgent need of an enriched preschool educational experience called Head Start. I hope the President, the administration, is listening to you, because if they are, we'll have a much better chance of improving education and improving access to a health care system, and a whole host of other needs, that helps the whole individual and helps make young people prideful, independent, and successful in school, which is by far the best antidote to drug addiction. I thank you, Mr. Chairman.

The **Chairman**. Thank you, Mr. Scheuer, for your wonderful contribution.

Mr. Coughlin.

Congressman **Coughlin**. Thank you, Mr. Chairman. I understand that I missed the testimony because I was on the train. Although, I was not here to hear it, I am familiar with it. Let me say that one of the welcome parts about President Bush's strategy as developed by the Director Bennett, there's a reassured emphasis, a shift in emphasis to prevention and treatment. So that's the reason these hearings are so important up here. My questions are directed to Mr. Nadel and Mr. Webb, primarily.

First I'd like both of you to address the availability of treatment slots and whether they are attainable, forgetting for a moment the quality of the treatment. Then separately address the question of what percentage of those who receive treatment go through the treatment process, complete the process and what percentage appear to be recidivous and go back and not succeed in treatment. Would you address those two issues for a moment?

Mr. **Nadel**. Sure. In terms of the waiting list issue, we looked at 24 clinics and found 10 that had a waiting list. But in terms of the overall number of people on the waiting list, more than half of those were accounted for by one clinic. We note that in New York, a survey by one provider, I believe it was in 1989, found about 600 empty slots. It's our finding, that while some clinics do have substantial waiting lists, part of the problem is one of communication and, of course, there is a problem of location. But, we now find an overall systemwide shortage. Another problem with waiting lists, Mr. Coughlin, is that we found, for example, in one clinic while they had a long waiting list, they didn't take people off the waiting list who may well have found treatment elsewhere. So, the waiting list really needs to be updated very, very frequently for it to be meaningful.

In terms of treatment outcomes, we found that after about 6 months of treatment, you have roughly about 60 percent of the patients remaining in treatment for longer than 6 months in our clinics.

Congressman **Coughlin**. About what percentage had successful outcomes?

Mr. **Nadel**. Well, if by successful outcome——

Congressman **Coughlin**. I know that's hard to find.

Mr. **Nadel** [continuing]. Just taking successful outcome to mean, for the moment, being free of heroin, we found about roughly half of the clinics, you had heroin use exceeding 20 percent—ranging anywhere from 22, 23 percent, to 50 percent.

Congressman **Coughlin**. Mr. Webb, you care to comment on those?

Mr. **Webb**. Yes; thank you very much. I've only been on the job for about 6 weeks as Governor Cuomo's new director. I've asked the same questions you've asked. What works, what doesn't work, what's cost-effective, what should we be doing? It's only recently that we've had the increase in Federal dollars for expansion of treatment. New York State and local government has really been bearing the brunt of almost $300 million of treatment activities. There hasn't been a new methadone clinic in 15 years. We haven't expanded the overall residential capacity in the last 10 years, we've just not been able to kind of mount those resources, largely due to two things. First, the lack of Federal reimbursement for individuals who are drug abusers and alcohol abusers, in terms of meeting the SSI definition of disability. Second, the Medicaid opportunities to bill for these kinds of services. Only recently have we seen from Congress and from the President, an increase in the block grant.

So, in many ways what we're trying to do is ask those very, very same questions. Let me say, though, recently, Wednesday of this week, a major national study was put out called "Treatment Works." What we are finding is a lot more information about the effectiveness of intervention in terms of drug abuse and alcohol abuse. What I find, though, in the methadone, we're dealing with a very complex situation. Many individuals continue to use other drugs than the heroin. Many of them have alcoholism problems, many of them are HIV positive, TB, hepatitis, sexually transmitted diseases. We have a situation that is a healthcare problem, a social care problem, an addiction kind of problem. It is an incredibly complex situation to take a person who's been on the street, using heroin, a variety of other drugs, and to get him into treatment.

So, one of the things I'm calling for in this major overall of methadone, is a healthcare strategy, a social care strategy, and a service/delivery strategy to help these individuals move from where they are, to where they need to be. The average cost per person in existing methadone is only $3,500 a year. Just think of that. That's the most remarkable thing, and we're still trying to do it and we don't do it well enough, by a long shot.

Congressman COUGHLIN. Thank you, let me ask one further question of Mr. Webb. Would you support the administration's proposal to require States to have a statewide treatment plan, including program performance standards for the slots that are federally funded?

Mr. WEBB. Well, the Governor's, we're already on our way. The Governor called for a huge interagency council at the State level last year, we've already issued that plan, we're well on our way to developing a statewide treatment plan, the Governor's called for an increase in 10,000 residential beds, over the next 3 to 5 years he's calling for an increase in 20,000 day services programs and almost a 15-percent increase immediately this year in prevention programs. So, we're well on our way to do that.

Congressman COUGHLIN. Would you agree with the planning that the President's legislation has asked for?

Mr. WEBB. If they're ready to pay for it, they can do the planning. I have a very simple kind of strategy here, when the State of New York pays for almost all of the programs, we should control the distribution of resources, what comes in what goes out. We haven't done our job in terms of some of the overall attention. I welcome the efforts, I've talked to Mr. Bennett's people in terms of expansion programs. Finally, we're starting to see the kinds of resources for treatment expansion and we welcome that. We are agreed to access those funds, and with those kind of increase in funds, I'll work cooperatively in establishing measures. We're not going to be dictated to. We'll work cooperatively, collaboratively, in terms of looking at these measures.

Congressman COUGHLIN. Thank you, sir.

The CHAIRMAN. Mr. Towns.

Congressman TOWNS. Thank you very much, Mr. Chairman. I would like to address this question from the GAO. Did the study consider the sizes of the clinics when looking at problems in the patient population. In other words; did dealing with 100 patients in a clinic versus dealing with 700 patients. Make a difference in the kinds of problems a clinic would encounter?

Mr. NADEL. We did not find a clear relationship between clinic size and ah, and outcome. We tended to be at some of the larger clinics, generally all our clinics with a couple of exceptions, were over 200 patients, because we were trying to capture as many patient records as possible. But our's ranged from roughly 200 to 700 and there was no clear relationship as to whether big was better or worse. I think a more substantial problem than size, per se, is counselor ratio. There we found that it ranged all the way from one counselor to 15, as I said, to 1 to 96. So that's probably the more telling issue of size.

Mr. TOWNS. What about the pickup schedule? For instance, the DEA talks about diversion, did the study showing differing levels of diversion based on whether a patient picks up two times a week, three times a week, or five times a week? You see I'm looking at the pressure on the methadone providers. You point out that there's not been a program that's opened in the last 10 years. I'm cognizant of the fact that two clinics have been cited. But I can't forget about the pressure of having waiting lists patients to get in, and for people to want to help them to get in. That pressure will force clinics sometimes, to perhaps take in more patients than they would be able to take in ordinarily. Did you see the shortage of treatment slots as a factor in the level of diversion?

Mr. NADEL. We didn't find that clinics that had more take home privileges had more positive tests for heroin. But the complicating factor is that, the take home privileges are generally given to patients who are in treatment longer and if patients are in treatment longer, you're generally getting a more compliant patient. We just didn't do the kind of clinical study, I think, that would be necessary to really get at that important question you're asking.

Congressman TOWNS. Yes; go ahead.

Mr. WEBB. Mr. Towns, picking up on two points. First, I was saying earlier that what the Federal Government can do to help us is to evaluate exactly those kinds of questions, those clinical kinds of studies, that the GAO is suggesting.

Let me say a different point, about size. Because we haven't been able to get one open, primarily because resistance of neighbors, we tended to concentrate more of the people and just a volume of people coming in and coming out and loitering and some of those other kinds of things, I can understand how the neighbors and the communities are saying, what's going on here? So, we, we're kind of in many ways defeating ourselves as we're trying to help some of these people get off the street and get into treatment.

Second, the counselor ratios. Absolutely. The service is available, what can you do for $3,500 a year in terms of those? The third thing is HIV and AIDS. Sixty percent increase in AIDS cases in the State of New York are from IV drug users. We have a situation here with individuals coming into methadone, we need an outreach and an expanded program to help facilitate these individuals coming into these clinics to get services, not only for the methadone or other health problems, but clearly HIV and AIDS. One of the things we are revamping with Dr. Axelrod and myself, an AIDS outreach effort to help deal with that incredible difficult problem and in the increased death rate, the increase morbidity related to AIDS along with a continuing use of drugs, is of a major proportion. So, we need to deal with that situation at the place in which these individuals are getting served.

Congressman TOWNS. I agree with that. We need to begin to think about and implement some different kinds of treatment programs. Rather than to try and open facilities in the neighborhood, why can't we begin to use existing clinics and hospital settings that close at five o'clock? Why can't we begin to treat methadone patients in the afternoon in those facilities? Then we wouldn't have to worry about opening a new clinic to control the situation. You have the security staff in the hospital, back up health care facilities and all of that on the premises.

Mr. **Webb**. Money in the hands of these programs and one of the things we have going for us, at many of these programs, are hospital based and hospital run. We can't have a referral system into that health network which they are already doing. We need to expand the set of referrals so we can maximize existing resources without necessarily already overburdening a healthcare crises in our country. But we have to, at the same time, because these individuals if they can't get the healthcare there, come back in through the emergency room, come in through the some of those clinics. We need to have a whole expanded healthcare strategy with many of these individuals who are accessing methadone.

Congressman **Towns**. I understand that. I think that what I'm really saying though, where we differ, is that I don't believe that opening up clinics in the neighborhood is the best option. On the other hand, I don't think anyone would object to seeing people being treated in a hospital setting. The hospital is an existing facility, one that already has the community acceptance support. We would be talking about an office that would close at four or five o'clock then at five thirty would start treating methadone patients in that same facility.

Mr. **Webb**. Here's the dilemma, Mr. Towns, we have 30 clinics in Mr. Rangel's district, 5,500 individuals in methadone. The problem is that in many of these hospitals and clinics, not only aren't they open after four, but they're not as accessible, so I have a real problem. How do I reach into certain communities where we have a concentration of drug problems and get that outreach. We need access points, so it's just not we need more points of access and outreach to get people into care, get people into treatment. So we do need expansion, but maybe expansion not with having 400 or 500 people in a single clinic. Maybe something a little different.

Congressman **Towns**. I agree. Let me ask the GAO about something which I think is a very important point. When looking at the whole treatment picture for addicts.

Did you have an opportunity to look at the arrest records of patients prior to going with the treatment versus after being accepted into the treatment program?

Mr. **Nadel**. No; we did not do that, sir.

Mr. **Webb**. The study that just came out on Wednesday, there is a definite impact on felony arrests as a result of many individuals coming into methadone.

Congressman **Towns**. I didn't hear that last answer.

Mr. **Webb**. National, national study that there is a reduction, people coming into methadone, getting methadone, there is a definite study that shows that there is a reduction in felony arrests as a result of people coming into methadone.

Congressman **Towns**. Well, I think that that's an important point and we should not lose sight of that factor.

Mr. **Webb**. That's a major point.

Congressman **Towns**. Very important point.

Mr. **Webb**. Absolutely.

Congressman TOWNS. Thank you very much, Mr. Chairman, I have no further questions.

The CHAIRMAN. Mr. Sensenbrenner.

Congressman SENSENBRENNER. Thank you very much, Mr. Chairman. Mr. Haislip, let me start with you.

Where is the diversion of methadone coming from, is it coming from the doctors and the other healthcare patients, or personnel, or is it coming from the patients?

Mr. HAISLIP. I believe virtually all of the diversion is coming from the patients because for many years now, we have had a regular program of inspecting clinics. DEA investigators do inspect these clinics on a scheduled basis, and I think the consequence of that is that there is relatively little diversion occurring as a result of the clinic personnel, as we had at one time seen. So, I feel comfortable in saying that the diversion is occurring from the patients who have been entrusted with medication to take away from the premises.

Congressman SENSENBRENNER. What kind of a procedure can be developed to spot those patients who are not using the medication according to the instructions of the physicians and other personnel at the dispensing point?

Mr. HAISLIP. Well, one of the problems that we've seen here is that the procedures and standards which are in place are not utilized. For example, when patients test positive for other drugs of abuse which shows that they are still involved in the illicit drug traffic. Or when they fail to test positive for the methadone that they are supposed to be taking and so forth, well, that obviously merits disciplinary action and certainly those patients should not be entrusted with any medication to take away from the clinic that they may sell to others. My agency, I regret to say, doesn't have the authority to establish the standards with regard to medication that's given to take away. So it's a bit of a handicap for us there. But, nevertheless, I think it's not a question of standards so much as it's a failure to apply standards that do exist.

Congressman SENSENBRENNER. Yes, but as an enforcement agency, obviously, you do have to enforce the standards that are on the books. What's wrong with some type of procedure where if you don't test positive for methadone, you've got to come in and ingest the methadone on site—in 100 percent of the circumstances. Now, I would guess that if you test positive for other types of drugs except heroin, there might be some legal room that would be advisable, but not too much. How about something like that in the mill so the people who are going out on the street and selling their methadone and using the cash to buy other drugs, end up taking their methadone in a supervised setting, and those who have a track record that shows that they've been able to responsibly, legally handle the methadone won't get punished?

Mr. HAISLIP. Well, Congressman, I think that you have a very important point, it's a point that I try to underscore and that is that methadone doesn't serve any purpose, doesn't work absent this kind of rigorous management and discipline and dedication to the treatment objectives. When there is no discipline like this, instead of being a service, it's a disservice and so I think what you're saying is correct. This is part of the problem that we see, a failure to do this.

Congressman SENSENBRENNER. Now, Mr. Webb, it seems to me that since you are the regulatory and the substantially funded agency for these types of clinics in the State of New York, you can use your dollars, I think, more effectively to get the message across than Mr. Haislip and the DEA in attempting to revoke licenses. How do we do that?

Mr. WEBB. You say we can get peoples attention when you control the dollars?

Congressman SENSENBRENNER. Yes.

Mr. WEBB. Let me try to put it a little differently—look at it from the individual addict's point of view. First, the addict comes for methadone treatment. We need to look at what kind of health care review of this person, what research is going on to determine what level of methadone is needed. We can use research and their is substantial research going on that you can try to get those maintenance doses down to smaller and smaller levels. Therefore, the volume of opportunity—remember the drug world—it's always opportunity isn't it, it's always opportunity. So if you can reduce that opportunity but at the same time increase good medical healthcare, at the same time, then you reduce that opportunity, that's No. 1. No. 2, distribution. How tight is that distribution? When someone shows up, how good is the observation and inspection in terms of injection? How clever are we because, remember, drug is what I found, everything has a price everything is an opportunity, and our street researchers, our individuals who are ex-addicts, who know the street, there's all kinds of incredible techniques to divert, even the ingestion of methadone, with cotton in the mouth and a lot of other kinds of things. So we have to be smart about that, so that's the third point of contact and observation. The fourth point is when it does, if it does get diverted out on the street, what are we doing to interfere with that particular opportunity in that market situation.

So, I see it as a continuing effort of increased inspection, formalization, testing, discipline, and using those dollars in very effective ways.

Now, let's look at the other end. Say what happens if a person's on methadone for, say, 4 or 5 years, full time employment. Shows clean on a regular basis. Why shouldn't we be able to work with that individual in a little different way, than the person who shows up for the first time. So I think we have to have a fairly different approach. We shouldn't have one shoe fit all kinds of approach. I can even see a very different take home policy, a very different kind of urine testing policy, for someone who has remained stable over a period of time and has a stable working family relationship. Remember 30 percent, 30 percent——

Congressman SENSENBRENNER. It seems to me that to put a stop to the diversion that is the subject of these two show cause orders that the DEA has served at the facilities in the last week, that what we've got to do. In other words, we've got to be monitoring the patients who get the methadone and find out who's abusing it. Because I agree with Mr. Gilman, it's not the job of the hospital to police the 10 block radius around the door where the methadone is passed out. Looking at the allegations into the show cause petitions, there seems to be some pretty sloppy recordkeeping here. Now, whether there's a cause and effect relationship between the sloppy recordkeeping, which I admit cannot be excused, and the methadone being diverted out on the street, there's a real big question. I don't think any of us here today, have the answer to that. What we've got to do is to zero in on getting at the bad results and at the people who abuse the methadone they are being given and selling it on the street, but for their own profit to feed their own drug habits, rather than using a blanket swipe to say that the system is bad. There are some people in the system who are bad, whether they be providers, record keepers or patients, but the whole system, I don't think, is bad.

Mr. WEBB. Right. That's why 6 weeks ago, we conducted six unannounced visits on the same day in six different clinics, when I first took office. It's exactly that point. We're going to be there, we're going to be on this case from the street, into the clinic and into the quality of care, we're going to be there.

Congressman SENSENBRENNER. You know, in my State, we had a big scandal about 10 or 12 years ago on nursing homes. There are good nursing homes and bad nursing homes, just like there's good and bad of anything else in our society. Once the State inspectors got on the nursing homes and made it quite clear what was expected of them and what records they were expected to keep and what they were supposed to produce should there be an inspection, things got cleaned up. It seems to me, at least in terms of what we've talking about here today, we're about at that point in methadone clinics.

Mr. WEBB. It's the same situation.

Congressman SENSENBRENNER. Thank you.

The CHAIRMAN. Mr. Shays.

Congressman SHAYS. Thank you, Mr. Chairman. In my district I probably have a few methadone clinics in a wider area than the Chairman has. You're saying you have 35,000 plus clients whereas we probably have a few hundred. In my judgment, we probably don't have the kind of problem that exists in the city, but it's something I'm going to be checking out.

This panel has set a very obvious goal that we've got our work cut out for us. Things are really bad. It poses one question which I don't want to spend a lot of time on because I really do want to get to the next panel. What I want to know is, very briefly, how did things get so bad? I'm wondering if it's just that it seemed like such a small part of the program in the overall picture that it just didn't get our attention. But how did things get to this point, very briefly?

Mr. NADEL. We didn't look at trends but in everything from defense to social programs, GAO has found that sloppy administrative procedures lead to sloppy programs, and there has been a real lack of effective Federal oversight.

Congressman SHAYS. Can I just see if all of you gentleman, basically, agree with the GAO report? You don't really dispute it?

Mr. HAISLIP. It's fairly clear.

Congressman SHAYS. So, the stage is set for what we do. May I also ask Mr. Haislip and Mr. Webb, if you both agree that the program can be a working program as a mix to the full picture?

Mr. HAISLIP. I agree that it can be if there is this kind of rigorous adherence to goals and rigorous discipline in management.

Mr. WEBB. I can go much beyond that. We have about 250,000 individuals who are heroin addicts in the city of New York, we reach in the methadone about 35,000, we have a long way to go. It is an entry port, it is the deal with that opiate. We have a much bigger problem. That could be the outreach, that could be the gateway into a lot of other services. That's my job. I have a practical problem, I got 35,000 people in need of service and another 200,000 yet to get served.

Congressman SHAYS. But you're not saying that every drug addict should be getting methadone?

Mr. WEBB. No; not at all, in fact that's what the Governor's called for is a balanced approach. Expansion of drug free residential program, detox, ambulatory care, by a long shot. One shoe doesn't fit this whole problem. We have to have a very differential kind of service delivery healthcare initiative in this area.

Congressman SHAYS. Mr. Chairman, that's all I need to ask I'd just like to get on with the next panel.

The CHAIRMAN. Let me thank this panel and underscore that none of us are talking about providers that are anxious to help these sometimes hopeless victims of addiction. Mr. Webb, in answer to Mr. Towns question about the reduction of felony arrests?

Mr. WEBB. Yes?

The CHAIRMAN. Will you not agree that many felony arrests involved people trying to get money to buy heroin for their habits?

Mr. WEBB. Yes.

The CHAIRMAN. If methadone is given and substituted for heroin or as a supplement to heroin would that not cause you to think that there might be a reduction in the need to commit crime to keep up a habit?

Mr. WEBB. Correct.

The CHAIRMAN. In many of these cases, isn't it so that the addict really doesn't go into these centers to to stop taking the heroin, but rather, to reduce the amount of heroin he needs?

Mr. WEBB. I think that's a complex question.

The CHAIRMAN. But I didn't mean complex, I meant isn't it true that many of the patients—this is the result of our investigation—are in the clinics, who are taking methadone and also taking heroin?

Mr. WEBB. Some are, some are continuing to use coke, some are on alcohol.

The CHAIRMAN. Exactly, and so we are really supplementing habits, in many cases.

Mr. WEBB. I'm not, I'm not really prepared to answer that, Mr. Chairman.

The CHAIRMAN. Yes you are, Mr. Webb. I don't like the answer any more than you do. But you know it, and I know it and the fact that we haven't had resources to evaluate these programs is not going to change it. You see, why we are going to have to face up to this because the Federal Government which has not participated like it should have, will be participating. The fact that we have had no accountability does not relieve the State of it's responsibility. We are dealing with a substitute drug that's dangerous.

Mr. **Webb**. But effective under controlled circumstances.

The **Chairman**. Exactly. We're talking about people dispensing it knowing that the patient is on other drugs. It's a very serious thing. You've only been on the job 6 weeks, and it seems like I've been on the job 60 years, but ultimately, we're going to have to say that this is a modality that we're going to have to use, we're going to have to control it, and that the government is not going to be a partner in the distribution of a dangerous drug merely because another drug is illegally brought into this country, and unfortunately, that's our task.

I want to thank you for assisting us in this and I hope our last panel will, indeed, give us more directions to what we can and should be doing.

The next panel, are the activists that are in the field of providing treatment, that are on the front line in trying to expand the availability of treatment and I'm certain, would agree with us that we're talking about treatment with rehabilitation and supportive services. Dr. George Woody, Chief of the Substance Abuse Treatment Unit, Philadelphia Veterans Affairs Medical Center; Mr. Mark Parrino, administrative director from Gramercy Park Medical Group and president of the Northeast Regional Methadone Treatment Coalition; my good friend Dr. Robert Newman, president of Beth Israel Medical Center; and Dr. Bertram John, who is the program psychologist of St. Mary's Hospital of Brooklyn Addiction Service Department.

All of your statements will be entered into the record and you can highlight the testimony that you would want the committee to hear. It has been brought to my attention that Dr. Woody, who I was calling first anyway, has to leave by noon, we'll take that into consideration. You have the floor Dr. Woody.

STATEMENTS OF GEORGE E. WOODY, M.D., CHIEF, SUBSTANCE ABUSE TREATMENT UNIT, PHILADELPHIA VETERANS AFFAIRS MEDICAL CENTER; MARK PARRINO, ADMINISTRATIVE DIRECTOR, GRAMERCY PARK MEDICAL GROUP AND PRESIDENT, NORTHEAST REGIONAL METHADONE TREATMENT COALITION, INC.; ROBERT NEWMAN, M.D., PRESIDENT, BETH ISRAEL MEDICAL CENTER; BERTRAM JOHN, PH.D., PROGRAM PSYCHOLOGIST, ST. MARY'S HOSPITAL OF BROOKLYN ADDICTION SERVICE DEPARTMENT

The **Chairman**. You have to leave the building by noon?

Dr. **Woody**. I'd like to catch the one o'clock metroliner.

The **Chairman**. OK, fine, that's good. If there are questions, may we conclude the questions with you before we go to the rest of the panel?

Dr. Woody, you may proceed.

[The statement of Dr. Woody appears on p. 118.]

Dr. **Woody**. I'd like to state an overall impression about the hearings and then address the specific issues that you requested in your letter.

My overall impression from sitting here this morning, and from reading about the issues involved, is that the hearings are focusing attention on very important aspects regarding the delivery of methadone treatment. I think that one of the most important aspects, that of increasing the quality of treatment, has come up in many of the discussions by the previous panel. That includes controlling diversion of methadone, attracting and retaining good people to the treatment field and upgrading treatment facilities, which I understand have deteriorated quite a bit in many places. I believe that there has been a deterioration in the quality of many methadone programs during the last 10 or 12 years, and that could, perhaps, be related to the decreases in funding for methadone programs which have been mentioned. As I read the figures, the funding levels decreased substantially, allowing for inflation, between 1975 and 1984. By 1984 they were, perhaps, only a quarter to a third of the levels of 1975. I believe there has been some additional restoration of funds, right now and perhaps Dr. Schuster can speak to that point. They're probably back to the 1975 levels of present, but that is the case in a situation where treatment has become much more complex, as a result of the problems associated with HIV infection and cocaine. So, the providers in methadone treatment are faced with many more probems now than they were in 1975, and the resources are perhaps approximately equal with the current restoration.

Those are some overall impressions. On the question of diversion, I believe that diversion is the Achilles heel of methadone treatment. It is an ever-present potential problem, but it is very controllable by administrative management. I think it's impossible to avoid diversion completely, but it can be kept under good control so that it does not become a public health issue. The data presented from New York City simply indicate that too many take-home doses are being dispensed. They're certainly being dispensed to the wrong people.

In the written statement which you received earlier, I made suggestions about how to reduce diversion. One is to make sure that all the clinics are open 7 days a week, and that they are funded to operate that way. If a program is treating 5,000 people for example, and is only open 6 days a week, that program is automatically dispensing 5,000 doses of methadone every week with no prior screening for any of the patients. In that way you can distribute as many take-home doses in one day as are distributed for the entire week. Another important part of controlling diversion is doing regular, observed urine testing. People who are receiving take-homes perhaps should receive two urine tests a week, and if their urine tests positive with illicit drugs, they should not be given the take-homes. There are a number of other suggestions, and all require work, drug counseling, good administrative and internal coordination within the clinic. I agree with the GAO statement that when the counselors have more than 35 patients, it's very, very difficult to provide good treatment and monitor those sorts of issues.

Another point is regarding the efficacy of methadone treatment. This was discussed by all the speakers. There is overwhelming evidence that methadone can be a highly effective form of treatment. Recent studies have looked at methadone treatment as a means of reducing the behaviors associated with HIV infection and reduce HIV infection rates themselves, have found evidence of significant changes from methadone treatment. These studies found significant reductions in a range of AIDS-risk behaviors including sharing needles, injecting drugs, and even sexual behaviors that would put individuals at risk. So, I think that the evidence is very, very strong, that methadone can be a very effective treatment modality and currently, there is very good evidence that methadone treatment can reduce AIDS risk significantly.

Regarding research data pertaining to the interim proposal, there are studies which indicate that drug counseling helps. Generally, more services have been associated with better outcomes, particularly for certain types of patients. There's also evidence that program structure helps and that the methadone dose helps, particularly in reducing heroin self-administration.

The project that is being conducted at our center, which was mentioned in the GAO report, is one that's looking at outcome in individuals who receive three different levels of methadone treatment, once they are in treatment. These levels are: minimal services which is methadone and only one brief counseling session each month, versus standard services which include one counseling session every week or two, and enhanced services. Preliminary data indicates better outcomes in those who receive the standard and enhanced services that in those who receive the minimal services. Therefore the data, and it is very preliminary, indicates that those who are getting minimal services are not doing nearly as well as those who are getting standard services. However, this project is not a comparison between minimal services and no treatment. It is a comparison of what would happen if minimal services were to run side by side with standard or enhanced services. The early data is consistent with the idea that better outcomes are associated with provision of more services.

Dr. WOODY. I believe the interim plan is a step backward. The exception might be that nothing else is available. That's the only situation in which the justification for even trying interim treatment exists. In other words, literally nothing else is available. Therefore, in evaluating the interim proposal, I find myself looking to see if no alternative is available. I do not know New York, I'm from Philadelphia, but I talked to Dr. Primm about this issue. He said that he checked around and, in his opinion, there were slots available in New York City. On Wednesday I called a friend who runs the Bridge Plaza program. He had 50 treatment slots available. He called several other programs and they all had open slots. So, I do not see a lack of availability of methadone treatment based on data produced by the individual that I have talked with though, certainly I have not surveyed programs as intensively as the GAO. I would say, that if too many programs are closed down because they are unable to comply with regulations as a result of administrative actions that could be taken, there might develop a need for interim treatment as a holding pattern to get people into new services that are being rebuilt or restructured.

I guess my major issue with the interim treatment proposal is that we're putting so much energy into discussing something that is not as good as standard services which need a lot of improvement themselves. Why shouldn't we put our energies into improving the quality and the delivery of service? I think that's where the major effort should be. Trying to do better, not trying to do work by setting up something that is inferior to what we know can be done. Why not strive to do better?

The CHAIRMAN. Well, thank you, Dr. Woody, and I agree with you, that we should be talking about quality care not interim care and that's the reason why we have a lot of people who are policymakers here listening to your testimony.

The question of slots being available or not being available, it would make sense that if the providers of interim care were being paid based on the number of people they had in their program, and if the patient really did not want rehabilitation, but methadone, that that would be a convenient relationship where one would say no slots are available, wouldn't it?

Dr. WOODY. It could be, if those two things occurred together, but I think that, you know, to what degree that mix would be played out is very, very hard to determine.

The CHAIRMAN. Well, let's you and I mix it. Do not institutions get paid on the number of patients that they have, reimbursement?

Dr. WOODY. I am not certain that I believe that's true.

The CHAIRMAN. OK, well, assuming that is true for the purpose of the mixture.

Dr. WOODY. Right, yes. I can see how that can play——

The CHAIRMAN. Then you have on the other side, would you agree, that many heroin addicts volunteer to go into these programs not for the purpose of getting off of heroin but for the purpose of getting methadone?

Dr. WOODY. I think if a program is not restrictive enough about take-homes, it is very possible that people will enter that program with the intent of receiving take-home doses which they will receive and sell.

The CHAIRMAN. Well, based on what you've heard, based on your experience and based on what you heard today, would you not believe that many of the patients want the methadone and not rehabilitation?

Dr. WOODY. I believe that heroin addicts are ambivalent about giving up drugs. That's generally true for any one that's addicted to any substance including alcohol, heroin, anything. Their response to treatment depends on the degree of that ambivalence along with the quality of treatment itself. Some people don't want to give it up at all, and other people want to give it up a lot, and there's a mixture along that range. It certainly——

The CHAIRMAN. Included in the mixture are the heroin addicts that don't want to give it up at all?

Dr. WOODY. I think that——

The CHAIRMAN. That want methadone?

Dr. WOODY. Well, you have to ask why do they want methadone.

The CHAIRMAN. Because they want to reduce their heroin addiction.

Dr. WOODY. Yes; that's true.

The CHAIRMAN. So, if we had people who are on heroin and they want heroin and they can't afford it, but the Federal Government and the State government are going to give them methadone to supplement it and take that mixture with somebody that get's paid to provide the methadone——

Dr. **Woody**. Yes.

The **Chairman** [continuing]. So, who's talking about a slot?

Dr. **Woody**. OK, well, I would say that if the heroin addict comes to the methadone program and wants to reduce their heroin use, because they're having a problem, whatever that might be, it's too expensive, or whatever, if they get on methadone for whatever reason, whatever their motivation may be, and they reduce their heroin, they will probably reduce their risk for HIV infection and probably reduce their crime rate. So, whatever their motivation is, if they are on the methadone, there might be an overall benefit to them and perhaps at some later time, a month or two down the line, along with counseling and rehabilitative efforts——

The **Chairman**. But when you figure that along with counseling then you and I are back on track.

Dr. **Woody**. Yes.

The **Chairman**. I'm saying that this clinic, that we're talking about, does not have counseling. They're selling dispensing methadone, and the addict wants the methadone.

Dr. **Woody**. Yes.

The **Chairman**. So, we're talking about why some people may not find those slots. But, it's interesting what you're saying. You're a medical doctor?

Dr. **Woody**. Yes.

The **Chairman**. Do you have any problem with a heroin addict coming in and getting a prescription to supplement his addiction without any counseling?

Dr. **Woody**. I have. Yes, I do have a problem with that. Especially, if they are not responding to treatment.

The **Chairman**. Forget treatment, he doesn't want treatment, he wants methadone. Do you need a lot of resources or Federal funds in order to determine whether or not doctors are dispensing methadone without any program that leads to rehabilitation? Do you have a professional problem with that?

Dr. **Woody**. Let's put it this way, I would be looking for outcomes. If that intervention reduces drug use and gets them a better job and does a lot of good things for them, I wouldn't have a problem if that was the outcome.

The **Chairman**. Doctor, doctor, a good job and doing a lot of good things in my unprofessional way, is rehabilitation.

Dr. **Woody**. That is my opinion, also.

The **Chairman**. So, let's use the same example.

Dr. **Woody**. Right.

The **Chairman**. I don't care what your doctors do, I don't even care what your failure rate is, if your attempt really is to help the person——

Dr. **Woody**. Yes.

The **Chairman** [continuing]. To ultimately be a productive citizen, OK?

Dr. **Woody**. Yes.

The **Chairman**. With or without methadone.

Dr. **Woody**. Right.

The CHAIRMAN. Now, what I'm talking about is the doctor that prescribes the drug, whether it's methadone or any other drug, only to get paid, without any consideration at all as to whether that patients addiction increases or decreases.

Dr. WOODY. Oh, I don't think that's very good. I don't think anybody would agree, that's not a good situation.

The CHAIRMAN. You don't need a lot of Federal Government oversight if a doctor's involved just to dispense or just to write prescriptions for drugs without any concern about the welfare of the patient. That is wrong based on professional standards.

Dr. WOODY. That is certainly less than optimal. If there is no concern for the patients welfare in the delivery of the services.

The CHAIRMAN. Less than optimal?

Dr. WOODY. Yes; that is——

The CHAIRMAN. I think it borders on being criminal.

Dr. WOODY. Ah, well——

The CHAIRMAN. I really do.

Dr. WOODY. Yes; I can see that.

The CHAIRMAN. If that patient dies of an overdose it could very well be that it was that legal drug dispensed that could have caused the death.

Dr. WOODY. Correct.

The CHAIRMAN. That drug is showing up at our emergency centers as being a part of the overdose of drugs.

Dr. WOODY. I think that can be controlled by restricting the number of take home doses.

The CHAIRMAN. Well, you normally give it to people to take home that you're trying to help.

Dr. WOODY. Yes.

The CHAIRMAN. You have to see some of the people that are taking home or taking the drugs outside of these clinics, selling it in front of the clinics——

Dr. WOODY. Right.

The CHAIRMAN. You don't have to be a doctor to know that these drugs never were going to get home.

Dr. WOODY. Exactly.

The CHAIRMAN. OK, any other questions of Mr. Woody before he leaves?

Congressman COUGHLIN. Could we hear the rest of the panel?

The CHAIRMAN. Well, he has to leave, that's up to Dr. Woody.

Dr. WOODY. I can stay, 12:20 will be OK.

The CHAIRMAN. OK, fine, right, you're right. The next witness, Mr. Parrino.

[The statement of Mr. Parrino appears on p. 216.]

STATEMENT OF MR. PARRINO

Mr. PARRINO. Good morning, Mr. Chairman, members of the committee. My name is Mark Parrino, I appreciate being invited to testify before this committee regarding the efficacy of methadone——

Congressman SHAYS. Excuse me, I've been so curious, if someone pulled the mic in front of the person, would we be able to hear him in the audience? Are you getting feedback?

Mr. **Parrino**. Is that any better?

Congressman **Shays**. That one I think is the transcriber, this one is the mic.

Mr. **Parrino**. This one.

Congressman **Shays**. I'll give up on it, but it just seems to me that they're not on, OK. But if you could just speak louder, I'm sorry, Mr. Chairman.

The **Chairman**. No problem, Mr. Shays.

Mr. **Parrino**. I don't think they're working.

Congressman **Shays**. OK, just louder.

Mr. **Parrino**. OK, I'll do what I can.

Congressman **Shays**. Thank you.

Mr. **Parrino**. I'm representing the methadone treatment providers in the 10 member States of the Northeast Coalition, and I've been directly involved in the provision of methadone maintenance treatment, since 1974, and have served as the Director of Gramercy Park Medical Group, Methadone Treatment Program, treating 400 patients since 1980.

A successful methadone treatment system has to flexible in it's structure and properly funded if it's expected to respond to changing patient characteristics. As you've heard in the first panel, the infrastructure of this country's methadone treatment programs is fragile. In spite of its success in effectively treating heroin addicts, which has been repeatedly documented in research findings for the last 20 years, methadone maintenance has barely survived years of inadequate funding and extremely negative public relations. It's always remained on the fringe of mainstream health care. In many respects, it's remarkable what has been achieved, given the available resources and prevalent social attitudes.

At present, the Nation's methadone treatment programs are experiencing considerable turbulence as a result of increased HIV infection among intravenous heroin addicts and increased cocaine/crack abuse.

The existing methadone treatment system must improve, it if is expected to treat heroin addiction in conjunction with these new realities. It must offer more comprehensive medical and counseling services on site in responding to the needs of the present patient population. The program managers and staff require enhanced professional training to reshape the treatment environment. The public must be better educated bout the value of methadone maintenance under this new set of circumstances. Performance-based standards of care should be developed and implemented to better guide the treatment system toward enhanced outcome. Finally, methadone treatment programs will require greater financial support to meet these objectives, which will be especially difficult in the era of cost containment.

I think it's important to note here, that expectations of outcome are directly related to the investment you make in the treatment system. You can't expect great outcome unless you have a good investment right at the inception.

On the issue of interim maintenance, which I have been asked to comment, the member States of the Northeast Coalition support the immediate and aggressive expansion of comprehensive methadone treatment services wherever they are needed.

In our opinion, the proposed interim maintenance rule represents a badly conceived public policy. It moves treatment expansion in the wrong direction at a time when more services need to be provided. The Northeast Coalition opposes the interim maintenance proposal for the following principal reason, focussing specifically on patient characteristics.

Most addicts used heroin as their primary drug of abuse at the inception of methadone during the 1960's.

At present, heroin addicts enter methadone treatment with serious multiple addictions, particularly to cocaine, crack, and alcohol. A greater number are homeless, uneducated, and unemployed. A greater number are seriously ill since patient morbidity has increased the incidence of HIV infection and AIDS. Patients are at greater risk for tuberculosis, pneumonia, and a host of other infectious diseases.

Some of the proponents of the interim maintenance have said that some care is better than none at all. We find this to be a specious argument that doesn't hold up to the current research findings. The Northeast Coalition has carefully studied the research findings of Dr. John Ball and his associates, "Reducing the Risk of AIDS Through Methadone Maintenance Treatment". In fact, the Coalition has submitted a copy of Dr. Ball's study in conjunction with this testimony.

[The study of Dr. Ball appears on p. 224.]

Mr. Parrino. Dr. Ball's conclusions indicate that better quality—comprehensive—methadone programs achieve a greater degree of effectiveness in reducing intravenous drug use, which is the critical objective in decreasing the incidence of HIV infection among such drug abusers. Dr. Ball's research found, and I'm going to quote:

> Marked difference in the effectiveness of various programs were observed: current intravenous use varied from less than ten percent to over fifty-seven percent of patients in particular treatment programs . . . It is a major finding that some methadone maintenance programs are markedly more effective than others in reducing IV drug use and needle sharing among their patients because these differences in treatment outcome are related to definite program variables. The more effective programs have high patient retention rates, high rates of scheduled attendance, a close, consistent, and enduring relationship between staff and patients, and year-to-year stability of treatment staff . . . Effective and ineffective programs, however, did not differ with regard to patient characteristics.

I think that's basically in support of the GAO findings. The Coalition has not reviewed any independent published date documenting the efficacy of interim maintenance regarding retention and treatment, the reduction of intravenous drug use, the reduction of other drug and alcohol abuse, and the improvement of the individuals well being.

In fact, the Methadone Coalition firmly believes that it is countertherapeutic and dangerous to offer fewer services with fewer resources to an even greater number of seriously ill heroin addicts. Many methadone programs are oversubscribed and understaffed. Admitting hundreds or thousands of HIV seropositive heroin addicts into such programs by eliminating basic quality assurance standards would be disastrous for all parties.

Patient loitering and methadone diversion are two other important topics that this hearing has chosen to focus on. They have created serious problems for methadone treatment involving loitering in the vicinity of the program and the diversion of "take-home" medication. Patient loitering is a program management-security matter. Increased surveillance of patients in the program area will not resolve the underlying problem of unemployment or dysfunctional behavior, but it will eliminate a visible symptom.

Methadone programs sustains their continued existence by keeping as invisible as possible to the surrounding community. This point needs to be made, it's unfortunate that a small percent of the patients are responsible for this problem.

A treatment program can prevent loitering by having well established policies, which are integral to the treatment process, and enforced by a well managed security complement. Security personnel must maintain an understated but active presence outside the methadone program to monitor patient activity within a well defined perimeter. I agree that the programs do have responsibility within the immediate area, but we are not a police force. We can't go beyond that immediate perimeter. An individual who is repeatedly observed loitering in the area should be evaluated for transfer into another methadone program. While this intervention may appear countertherapeutic for the individual patient, especially if the patient is discharged from care, it preserves the continued existence of the program for more motivated people. No treatment program can be all things to all people. A history of heroin addiction does not necessarily mean that the individual will always benefit from methadone treatment.

DIVERSION

A number of methadone patients will sell their medication to untreated drug users, who either do not need or want methadone maintenance or are unable to meet the established admission criteria. Making good quality treatment more readily available could reduce the frequency of this dangerous practice, since many buyers of illicit methadone would seek treatment. That point has already been made.

The illicit sale of methadone is a serious matter and has done considerable damage to the public's trust in the value of methadone treatment. A nontolerant individual can die as a result of ingesting an illicit dose of methadone.

In my experience as a program administrator, I know that some of the patients will sell their medication. Most of the patients take their medication as it's been prescribed. Gramercy Park Medical Group has a policy of discharging patients who are found to be selling their medication. The most unstable patients are compelled to attend the clinic each day while more responsible patients remain on reduced visit schedules. Weekly toxicology results are an integral part of the clinical decisionmaking process.

Some people believe that all treatment programs should open 7 days a week and that every single patient should attend the clinic each day. Research does not support this perspective. Punitive practices are not necessary and could be counterproductive. Responsible, successful patients, including people with full-time jobs, homemakers and students, would be driven out of treatment, and that is not the practice of responsible medical care.

Performance-based treatment standards, the last point I've been asked to comment on. The standards of methadone treatment programs vary markedly within cities and States as documented by Dr. John Ball and his colleagues in the aforementioned study. There is no nationally recognized standard of quality care. Some States arbitrarily restrict the amount of time that a patient can remain in methadone treatment, which is dangerous to the patient and jeopardizes his sustained recovery from heroin addiction. Other States limit the patients' methadone dosage to a predetermined ceiling regardless of the individual's medical needs, and this runs counter to the practice of responsible medical care. Some treatment programs make a practice of detoxifying pregnant women under the incorrect belief that the child will be better off. In fact, considerable harm can be done to both the mother and fetus. As a result of these practices and policies, patients are treated badly.

The Food and Drug Administration promulgated process review standards in 1974, which have either been adopted or made more stringent by single State regulatory authorities. These explicit standards monitor the presence or absence of predetermined record keeping elements. Process review criteria do not evaluate patient outcomes such as retention in treatment; the reduction of narcotic use through a proper methadone dosage; the reduction of alcohol and other drug use through counseling intervention; reduced criminal activity; improved physical health through the diagnosis and treatment of chronic illnesses; or the improvement of social functioning through vocational education, training and job placement. The Northeast Coalition supports the development of such performance-based criteria. At the present time, I am involved in a study, to develop such criteria through the Research Triangle Institute and the National Association of State Alcohol and Drug Abuse Directors. I'm a member of that performance based review panel.

The CHAIRMAN. Thank you. Dr. Newman.

[The statement of Dr. Newman appears on p. 237.]

STATEMENT OF DR. NEWMAN

Dr. NEWMAN. Thank you, Congressman. From the back of the room that eagle on the wall behind you looked as if it had been beheaded and it was, for a second, I thought maybe I was being given a subtle message, but I wasn't so easily intimidated. [Laughter.] It clearly does look like it's without a head.

I hope you have a more gentle fate in store for me this morning, Congressman.

The CHAIRMAN. Doctor, I don't know what's in your mind, but it's going to be very interesting to see how this develops. [Laughter].

Dr. NEWMAN. I think that we'll see. I'm very pleased to be accompanied today by Dr. Edmund Drew, who is the medical director of two of the Beth Israel methadone maintenance clinics. I have, as you know, submitted written testimony which addresses, I hope concisely, the specific questions which you posed in your kind invitation to be here this morning. Both Dr. Drew and I will be delighted to expand on any issue in that testimony as we respond to questions. I would like to very briefly, though, comment on the national TV broadcast last night that dealt with methadone diversion.

As you know, because I have had the privilege of testifying before you in the past, Congressman, I have never denied the problem of methadone diversion——

The **Chairman**. Excuse me, Doctor, would you assume that none of us saw that program and we just came in from Washington——

Dr. **Newman**. Is that a wish or an assumption?

The **Chairman** [continuing]. We did not see the program.

Dr. **Newman**. I'm sorry, Congressman.

The **Chairman**. I don't know whether it was national. Was it national?

Dr. **Newman**. It was national, yes.

The **Chairman**. I just didn't see it, and there may be other members who are unfamiliar with the program.

Dr. **Newman**. Congressman, you and I both have the distinction of appearing on that national broadcast. It basically concluded, on the basis of GAO findings, and DEA findings, that methadone was a terrible failure throughout the United States; it referred to methadone programs being a major part of the problem rather than a part of the solution, and it specifically referred to methadone programs as "pushers" of drugs. That, in essence, is the substance of last night's TV broadcast. As I say, I've never denied that there is a problem of methadone diversion; it's one that troubles me deeply. It's one that has to be addressed on many different fronts. Methadone programs themselves can and must do something about that problem, and I've outlined in my written testimony what we at Beth Israel do. I can assure you that we do it conscientiously and I think we do it with relative effectiveness.

In addition, law enforcement agencies at all levels, clearly, have a very major role to play in dealing with the diversion problem. If it were up to me, I would have a patrol car on every block where Beth Israel operates methadone clinics, and I would certainly not dissuade law enforcement agents from immediately arresting anybody and everybody who breaks any law, including the law against selling methadone. However, I don't believe that law enforcement agencies or hospitals or methadone programs will ever make a significant dent in the problem of methadone diversion. I don't think anybody will ever make a dent in the problem of methadone diversion, as long as all of the efforts are focussed or the supply end and not on the demand side.

We heard Congressman Scheuer, earlier today, talk about the failure of the national strategy on the war on drugs because of the overwhelming focus and attention and dollars which have been devoted to dealing with supply at the expense of the demand side. There is far too little attention paid to prevention efforts, treatment efforts, educational efforts and so on. If we're going to do something about the problem of methadone diversion, and I can assure you, Congressman, nobody wants to make an impact on that problem more than I do, we absolutely must also address the problem of demand. This is a demand by a very, very large number of desperately motivated heroin addicts who want treatment and need treatment. They know, as the GAO knows and has reported, that treatment that can make a difference between life and death, and yet they are turned away because every program in this city, and most other cities, is filled to capacity. I will address the issue of waiting lists in just a moment.

With regard to the GAO report itself, I've been in this field for twenty years but I have rarely seen a more convincing, dramatic testimony to the effectiveness of methadone treatment. The GAO found in 14 out of the 24 programs that they studied, that heroin use among patients in treatment only 6 months had been reduced to between 2 and 13 percent. This is not just a partial reduction in consumption. The GAO report said that 87 to 98 percent of these former hard-core heroin addicts, within 6 months of entering methadone treatment, had ceased using heroin. That's a phenomenal figure, particularly in light of the fact that so many programs do not give pharmacologically adequate doses of methadone, and also because programs are unable to provide the optimal level of staffing that we all would very definitely like to see. The results are really dramatic.

Finally, I have to admit that I was really deeply saddened by the portrayal of methadone programs as a major part of the problem, and as "pushers" of methadone. I say that, because that type of sweeping defamation is aimed directly at the extraordinarily dedicated, committed, and effective people who work in those programs and who are responsible for the successes that the GAO has demonstrated. These phenomenally motivated workers have accepted patients with problems that are among the most horrendous which face our society. Not only drug addiction itself, which God knows is bad enough, but the associated problem of HIV infection. These workers labor in clinics with patients who are very difficult to treat and they treat them well. The disservice done to them, Congressman, is absolutely devastating. In addition, the effort to expand treatment, to get more counselors, more nurses, more physicians to offer help to people who will die without that help, is extraordinarily difficult to begin with, I must say it has been set back further by the denunciation of programs and, by implication, of the people who work in those programs as "pushers". I'm really deeply, deeply saddened.

[Pause.]

Dr. NEWMAN. With the assistance of Dr. Drew.

The CHAIRMAN. Dr. John, from St. Mary's.

STATEMENT OF DR. JOHN

Dr. JOHN. Thank you, Mr. Chairman. At St. Mary's Hospital Addiction Services unit, we service over 1,600 patients. Over the past 19 years, we've worked with thousands of individuals who have explored a variety of forms of treatment, our experience convinces us that methadone maintenance provides the best, if not the only respective reality, for many persons addicted to opiates.

Unfortunately, the problems associated with methadone maintenance treatment can be far more visible and sensational than the fact that methadone maintenance treatment has vastly expanded the lifespan for many addicts. We share the irony that the successful methadone maintenance patient has to become invisible in order to remain successful. There is still an intense social prejudice against persons in methadone treatment; despite this, many of the goals initially set for this form of treatment have, in fact, been met.

When we examine the changes in lifestyle among persons in treatment for more than 1 year, we find that arrest rates fall, families regain the opportunity to stabilize themselves, and the craving for opiates and the lifestyle and activities related to the craving, are significantly curtailed. While we see methadone maintenance as a viable and effective modality for the treatment of opiate dependents, we are aware also that patterns of drug use change over time. More often than not, people seeking treatment tend towards multiple substance involvement and I think all of us have addressed this problem. In such cases methadone maintenance produces mixed results. At present facilities are simply overwhelmed by the growth in the number of multiple drug involved persons and treatment where resources are finite indeed.

In short, we recognize that treatment needs have expanded beyond the specific expectations designed into methadone maintenance treatment. What we have been doing has been embarking on the expansion of facilities to meet the challenges posed by the evolving nature of the drug problem and its impact on the individual, the family and the communities which we serve. We serve communities in central Brooklyn, impoverished communities where the problems associated with addiction are complex, indeed. We have attached documents relative to this effort for your examination.

[The documents of St. Mary's Hospital appear on p. 258.]

Dr. John. On interim maintenance. We are a part of the Northeast Methadone Coalition and we share the position reflected in testimony delivered by the Coalition's president, Mark Parrino, to the FDA and NIDA. The idea he argues, of treating a population with greater illnesses with less services leaves unanswered questions. "It suggests that we are incapable of handling the complex problems of drug abuse. We recommend that you reverse the position of the paper presented on that question." Assessing the effectiveness of certain operations. Over the years, the drug abuse population has changed. Thus, patients entering treatment have also changed. Patients come with an increasing number of problems, multi-addictions, homelessness, hopelessness, AIDS, and neglected health problems due to poverty and misguided focus fostered by drug abuse. These factors have necessitated addressing our operations more closely to assure that the wide variety of problems are addressed in a manner that would benefit the patient population as a whole. Yet, we try to maintain an individual focus. Addressing the effectiveness of our operations always has, and continues to be, an order of primary concern for us. Internal audits and reviews are methods we use routinely for evaluating our clinics effectiveness. Along with these are reviews from the New York State Division of Substance Abuse Services, the DEA, the FDA as well as audits and reviews by the hospital's Executive Office of Quality Assurance, and most recently the Joint Commission on the Accreditation of Health Organizations. Their recommendations have been incorporated and we enforce them to assure compliance and improvement in the delivery of service. We have developed an extensive training program for the use of our staff, and this is supplemented by an on-going program of in-service training by the New York State Division of Substance Abuse Services, which conducts training seminars which provide substantial exposure to refinements and advances in the treatment process.

We are particularly concerned with DSAS's report on evident methadone diversion at 229 Powell Street. We fully recognize the importance of caps to methadone diversion in New York City. By no means do we intend to minimize the seriousness of this problem or to deny its existence in our operation. We do, however, urge you to look at the larger picture which might help us all in dealing with the phenomenon.

There appear to be three main factors that contribute to diversion in our case. First, our methadone maintenance treatment programs operate within, primarily, residential areas. Behavior associated with diversion, gathering, loitering, multiple drug involvement, et cetera, is easily transferred from other areas in the community to the environs of the clinic where concentrations of people with similar interests already exist. Because our patients are part of an excluded group, both within and beyond their communities, there is an increased tendency toward street related activity including diversion of methadone and exchange or even sale of other drugs. The problem of loitering which fosters such activity has been complicated by the fact that many of our patients live within the immediate neighborhood of the clinics. The need is for smaller clinic sizes perhaps, and for greater community involvement with the treatment process. That we have tried to encourage and we think it is very important. We can with some assistance, with much assistance, broaden the range of community services we provide so that a positive link is established with the community we serve and our image in the community is improved. We need the effective support of communities in order to find durable solutions to this form of diversion.

Second, we have been designing a more family oriented treatment to increase the level and quality of services associated with methadone maintenance treatment. We found that the greater the family involvement the greater the chance for rehabilitation. A second issue with respect to diversion. Some diversion reflects the needs some individuals have to test their ability to function without methadone. There are substantial family and community pressure for individuals in treatment to detoxify, often very prematurely. This pressure often encourages some patients to experiment with medication. In the face of financial pressure on multiple drug users to sell or exchange their methadone. In addition, the methadone maintenance treatment model did not really anticipate the need for detoxification and the post-detoxification needs of patients. The problem of testing is exacerbated by this ambiguity in the treatment model.

We are impressed with some research done by Dr. Kreek at Rockefeller University, whose research is on pharmacological implications for detoxification. She suggests that detoxification for methadone be conducted over very long term—several months at least. A need clearly exists for more supplemental applications in maintenance, detoxification, and after care approaches. It is equally important to develop more effective guidelines for granting and receiving take home methadone.

With expanded clinic hours we could develop tighter take home policies, but even this would have very little value without effective after care.

The third issue, the most visible forms of diversion might be understood in the context of this factor: our patients represent an excluded group. To the extent that such exclusion exists, people feel invisible. In the present climate of multiple drug use, some people seek treatment whose drug of choice may not, in fact, be an opiate. We find this a particularly bothersome problem in the face of the current popularity of crack. Persons with a drug of choice other than an opiate are clearly more likely to divert their methadone. Our population is at risk for AIDS; persons living at the edge of life, and in the shadows, are more prone to desperate and high-risk activity. We see evidence of drug binging and experimentation in persons who test positive for HIV.

Finally, our population is for the most part, poor and under educated. Part of the pre-treatment lifestyle involves a view of drugs as commodities. The treatment process does enable most, but not all, of our patients to overcome this mindset. I think, Mr. Chairman, that this is a very important issue. Part of what we are treating is a lifestyle history involving the sale, the purchase and activities around the seeking of heroin and other drugs, and our focus is in part on treating this pattern. So, diversion comes into the clinics from the start. We are working to reduce this potential, this likelihood. The clinics continue to focus on integrating the services of community residents, the police department and their own staffs to address the problem at all levels. This includes increasing the awareness and education of our patient population. On an immediate basis, the clinics policy is to terminate from treatment any patient who is observed selling his or her medication. In conclusion, the efficacy of methadone maintenance as a form of treatment is undoubtedly established. However, what has to be done is to upgrade treatment staff, to educate community persons and to sensitize public officials to the many needs within the treatment system. Staff and patients both need to work in better surroundings and safer buildings. Persons working in the drug abuse treatment system get the feeling that not only is the addict treated with disdain but also the people who support efforts to improve life for them. We need to have you address more rigorously the need for public support for methadone treatment. We need to fight drug abuse on all fronts, not only on fronts that are pleasing or comfortable, we must strive to eliminate the bias and ignorance that exist.

We thank you for allowing us to be a part of this hearing, and to respond to your concerns. We assure you that we too share a number of your concerns and trust that together, we can improve treatment for substance abusers. We remain committed to the task. Thank you, Mr. Chairman.

The **Chairman**. Thank you, Dr. John. Dr. Drew, do you have any contribution to make to this discussion?

STATEMENT OF DR. DREW

Dr. DREW. Yes, I just have a few remarks that I'd like to make and a little clarification.

I think what's happening now, that Dr. Newman alluded to, is that I run two methadone maintenance clinics in Harlem, one of which is the interim clinic. I am the interim clinic doctor. I have been the interim clinic doctor since 1987, since its inception and I also am the doctor for one of the traditional clinics at the same time. I'd also like to make it perfectly clear, at this time, that I have no vested interest in methadone maintenance as the treatment modality per se, the singular treatment modality, because at the same time that I hold those positions, I am also Assistant Director of Medicine at Reality House, which is a program where we use methadone for MTA—methadone to abstinence—purposes. It's a program where we take patients who come out of in-patient detox and we try to give them counseling to keep them drug free. I'm a strong advocate of using the proper treatment methods, offering the drug addicted person the proper modality for that individual. To reach the maxima level of improvement that that patient or person is capable of at that time.

Also, I'd like to bring the discussion home a little bit. Wherever I go, when I testify, I sort of get disturbed when I keep seeing numbers and more numbers, because from numbers you see some magnitude of the problem but they don't really convey the suffering. I want to let you know right now that on my desk when I go back, there are six death summaries that I have right away. One of them involved a 37 year old mother who has just expired related to AIDS, with a child who has AIDS and she leaves behind a family of 7 children. I am concerned about the relief of suffering, and the methadone interim clinic as I testify, or as I answer your questions, will be along those lines. Talking to you about how the interim clinic really reduces suffering, morbidity, mortality, reduces the number of carriers in the community, for tuberculosis, for hepatitis this is what I'm about.

The CHAIRMAN. That's a very moving contribution, I'd like to ask you some—well, let me ask it now. If heroin was legal would not the dispensation of heroin provide the same type of relief that you're suggesting, Dr. Drew?

Dr. DREW. No, no.

The CHAIRMAN. No? OK, well that answers my question. Let me make it abundantly clear to this panel that for those doctors in clinics who are dedicated to trying to improve the quality of life of their patients, we certainly have come to the conclusion that methadone is an effective tool. I think all of the witnesses have indicated that it is only a tool. Without the support of services that would lead to a better quality of life, we are talking about a very dangerous drug. Now, if when we go to these emergency centers, we find someone who's died with an overdose and that overdose is cocaine, heroin, and methadone, we are concerned with how that methadone contributed to the overdose.

Now, some of us are fighting to make certain that heroin, cocaine, and crack are gotten off of our streets. We go to the Golden Triangle, to South America and I'm telling you that we're going after methadone here. We are concerned how it gets into the street. The fact that it gets into the street by prescription is a major concern to all of us. Doctors write those prescriptions—it's clear as to what we're talking about here. We're talking about how that methadone gets into the street and whether or not these programs are oversubscribed and understaffed in order to get reimbursed for the prescription or whether or not the dedication is so overwhelming that there are doctors who assume that dispensing this drug is just more important to ease the pain than it is to follow the law. The closer we get to just talking about treatment without quality, without standards, the closer we're getting to legalization of all drugs and that's the reason why I'm glad that you answered my question to you, Dr. Drew, the way you did. There are some of your colleagues that think differently.

So we are here to make certain that we support where services are provided to bring a resolution to the problem, to get your advice as to what we can do to make certain that where the distribution of methadone is adding to the problem that we know about it. Now, also, for doctors who work in poorer communities or live in poor communities, you do know that we have been flooded with doctors coming into our community with pharmacists that are providing drugs to our community that are paid for by the city, State, and Federal Government. These are licensed doctors and licensed pharmacists who, to me, are no different from any addict pusher. Indeed, they are worse to me, than the addicted pushers who are on the street. As I said earlier in these hearings, in every profession we have among us people that we wish not to be associated with. Always when a Congressman, a politician is indicted, a cop is indicted, we all feel, well, you're not talking about us, we hope. Nevertheless, we have an oversight responsibility when these dangerous substances are on our streets and when that diversion is based on the doctor or pharmacists writing a prescription.

Now, not withstanding what law enforcement people have said, I for one, don't believe that doctors, clinics, or hospitals have a responsibility to police their street to see who's selling the methadone. But I do believe, that where it is abundantly clear that those patients are there to get the methadone and not to get treatment, there is no question in my mind that many doctors and many institutions know that. To the degree that they assume the position that this is better than nothing, that is where we differ. I would just like to address those differences.

Dr. Newman, do you believe that a methadone clinic should provide methadone to a heroin addict that has no intention and has not indicated a desire to get off of heroin?

Dr. Newman. Congressman, would you allow me to just very briefly comment on your statement that preceded your question? I want to take the opportunity to agree with you most emphatically, and as a matter of fact, as a physician I am filled with even more revulsion, against physicians who do the type of things that you——

The Chairman. You know, they're in my community.

Dr. Newman. I assume they're in every community, but, Congressman, I can assure you——

The **Chairman**. I've never heard of any doctors coming forward in any way or read about anything happening to these doctors at all, have you?

Dr. **Newman**. Sir, I can assure you that they are not in methadone programs because, and this gets to a question you addressed earlier about reimbursement, to my knowledge there is no physician and no staff member of any kind working in any methadone program, funded in any way by the State of New York, who has a nickel of incentive with regard to the amount of money based on the number of patients that are seen. For my institution, and as you know I direct Beth Israel Medical Center, the contract with the State makes it absolutely impossible for Beth Israel to make any money whatsoever off of the methadone maintenance program. The contract funds the deficit that exists; there is no way to make a profit. I know that exactly the same type of contractual provision applies to every other program that is funded in whole or in part by the State of New York. Money making as an incentive, I'm convinced, does not apply to public methadone programs in New York State.

The **Chairman**. I hope that you might do a paper on that for me as relates to the methadone industry—and I'll help you to get information—and those who dispense methadone. That would be interesting. But you do know——

Dr. **Newman**. It would be a privilege to do that with you, Congressman.

The **Chairman**. But you do know that right next door to whatever clinics you operate, are other doctors dispensing other legal drugs. I mean, when you take a look at all of the drugs that are on my street, a large amount of those drugs are dispensed by doctors.

Dr. **Newman**. As I say, Congressman——

The **Chairman**. You know that——

Dr. **Newman** [continuing]. I agree with you and I'm filled with revulsion that colleagues of mine——

[Pause.]

The **Chairman** [continuing]. Approach, but I do expect that we show outrage, too, you know. Not just because somebody happened to mention methadone and we're outraged because we're talking about dedicated, public servants. Every time a Congressman goes to jail, I don't give a speech about how good I am, and so we ought to understand that my job is not to run around saying, You've done a great job and we don't know what we would have done without your clinic. My job is to provide oversight, where clearly, the State officials are saying they have not had oversight because they haven't had money. The DEA says that they have more important things to do. The General Accounting Office did it because I asked them to do it. So, you knew we were coming, and I think what we have to do is to get more cooperation in terms of excising these cancers that obviously affect the ability of those who want to do a good job from providing it without their reputations being damaged. Of course, you know, it was announced today—Ben Gilman made a point of it—that two of your clinics have been cited for methadone violations and one of them is in my district. Some clinics have been cited, and I would have thought that you might have wanted to talk about these things, but——

Dr. NEWMAN. I'd be delighted, Congressman.

The CHAIRMAN. Maybe it's the type of thing that should be responded to in the proper forum but since Ben Gilman was defending Beth Israel so vigorously before he left, I assumed that somebody else might ask the panel.

Dr. NEWMAN. I'd appreciate a moment to respond, if I might, to your specific question about that Beth Israel program. We shall certainly respond in due course in the manner that's been stipulated by DEA. However, I can tell you now that the findings in the show cause letter overwhelming are findings of a Food and Drug Administration inspection that occurred many months ago. There were "deficiencies," and I say that in quotes, to which we promptly respond. We indicated a plan of correction for each one. We have a letter in the file from the FDA accepting our plan of correction for each and every one of those "deficiencies" that were cited. I believe that perhaps this is an example of a communication problem between two agencies, because those deficiencies have been addressed by us, and our response has been accepted by the Food and Drug Administration.

The CHAIRMAN. That administration will be on the next panel.

Congressman SENSENBRENNER. I'd like to ask Dr. Newman some questions. I have the show cause order in front of me, and it appears that there are seven different types of record keeping violations that were enumerated in the show cause order. In one instance 37 percent of the records were not according to regulation and the second, 40 percent and the third, 62 percent, and the fourth, 22 percent, fifth, 16 percent, and the sixth, 33 percent, and in the seventh, 10 percent. Now, isn't that an unacceptable rate of the records not being kept properly?

Dr. NEWMAN. From my standpoint, sir, any deviation from any standard in any regulation is unacceptable. But, I think one has to view it in the context of a clinic that serves 230 patients, all former heroin addicts. The letter itself, the DEA letter to show cause, states that 90 percent have not used heroin. That finding is cited in the DEA letter threatening to close this clinic.

Congressman SENSENBRENNER. OK.

Dr. NEWMAN. But my deviation is unacceptable. We have responded to every one of those citations you indicated. Our response to each of those specific deficiencies has been accepted by the Federal Food and Drug Administration.

Congressman SENSENBRENNER. Now, that get's me to my next question, and that question is directed to all of the panel members. We all know that a large number of the people who go to methadone clinics take their methadone the way it's prescribed to them. They want to get off their dependance on heroin and get clean and lead a normal and productive life. I guess my question is, is there anything in the record keeping that would be determinative of a red light going on saying these are the people who are abusing the program and selling their methadone out in the street? Can a modem be devised that if someone does not test out in the proper way and the records are reviewed, that these are the people who ought to be looked at to see if they are properly using the methadone, or whether they are illegally fencing it someplace down the street?

Dr. NEWMAN. Absolutely, and there is such a mechanism and we at Beth Israel employ it very, very consistently. In the past year there have been 1,000 patients who have had their take home privileges reduced or rescinded entirely because of precisely the red flags you indicate. So, I agree with you 100 percent; there should be and there are red flags, and they are being utilized.

Congressman SENSENBRENNER. OK, that's 1,000 patients out of how many total?

Dr. NEWMAN. Out of 7,800.

Congressman SENSENBRENNER. So, you're talking about 12 to 13 percent of the patients who have been in Beth Israel have done something that indicates they are abusing the treatment that is going on and consequently their take home privileges have been reduced or revoked?

Dr. NEWMAN. No, sir, they are individuals for whom one of these red flags that you indicated came up which suggested that perhaps there is a problem, and that the individual should be monitored more closely. It does not mean that patients were caught doing something illegal. It was a question of heightened concern or suspicion, which led us to respond in the way that the Federal and State government regulations indicate we must.

Congressman SENSENBRENNER. I grant you that unless a law enforcement officer actually observes a transaction taking place, anything along the lines that you're talking about has got to be done by circumstantial evidence. Because that's the only evidence that's available. But it seems to me, when we're talking about one in eight or one in seven who are in the program not following the program's parameters, this is something that shows there is a generic problem involved where a good chunk of the people who are receiving methadone.

Dr. NEWMAN. Sir, again, I really have to disagree. The GAO report itself, in its study of New York City methadone programs, found that only 2 to 5 percent of patients were using heroin. Again, you asked about suspicion and not cause for concluding that there is wrong doing. The Federal and State regulations say there must be positive reasons for reducing the pick-up schedule, for instance having a job. If somebody loses a job because the store went bankrupt, pursuant to the regulations we have to review the take home schedule. I'm sorry if I misled you into thinking that one out of eight of our patients has a problem, is not following rules. Certainly, I did not mean to suggest that one out of eight is known, or suspected, of selling medication.

Congressman SENSENBRENNER. Fine. Let me ask the other two witnesses what type of cause and effect relationship there is between someone who's records indicate a suspicion and that person not going through the course of treatment that hopefully gets him off drugs.

Mr. PARRINO. The first issue underscores the use of intravenous heroin. Why does intravenous heroin use continue in programs? John Ball's study came up with this funding and the GAO study also talked about the matter. It's generally because a subtherapeutic dose of methadone has been prescribed for the patient. When you look at patient characteristics and we've alluded to HIV seropositivity, we've discerned to the fact that many have not been educated, we've talked about unemployment as well. The reality is, that when a patient is coming across our threshold, they're entering treatment with the best intentions. We have weekly toxicology reports that the staff can evaluate. If we see problems with a patient, if a patient is using other drugs, we address the matter. It is a significant issue of treatment. When we know that a patient has some difficulty, with drug use the program very much intervenes in dealing with that particular problem.

I talked about the issue of oversubscribed and understaffed programs. That was not the desire of the treatment programs. I think Mr. Webb alluded to it in his earlier testimony that said, the State had limited resources due to the lack of treatment programs being open. As a result, many people were put into one program site, and that's an unfortunate reality.

Dr. JOHN. I would add that at this point the prevalence of polydrug abuse means, for us, that methadone maintenance programs have been pushed into a position in which what we now treat is a far more complex problem then we were initially expected to treat. I think that the red flags that you're discussing, Mr. Sensenbrenner, the red flags that come up for us, they usually mean that there's a problem on which we must focus in the treatment programs, and there is no one else around to take up the slack. We are, in fact, stuck with the polydrug abuse problem.

Congressman SENSENBRENNER. The first panel very clearly stated, that it isn't the physicians or the providers who are responsible for the diversion of the methadone, it's the patients who are doing it. I think we all realize the Federal Government doesn't have unlimited money there, but there's going to be more money for this purpose diverted by Congress in the next fiscal year. It isn't going to be as much as you'd like or we'd like or a lot of other people who are knowledgeable about the issue's like. So the real question is, to try to devise some kind of a program short of the vast increased staffing needed to provide the counseling and the social services in an adequate manner, to figure out who are the bums who are not following the program and are using this methadone as a way to make money to feed a drug habit. Go after those people and see what we can do to put a stop to it. In that, we're all in this together because programs like this can't afford any more exposé's on the NBC nightly news. Now, I didn't watch it, I was taking my kids swimming when that was on, but I heard.

Mr. PARRINO. I didn't watch that either, and I'm glad because when I see those programs I get sickened, because it misrepresents, the good work that's done by the thousands of people who are really trying to reverse years of pernicious drug abuse. Methadone diversion is a problem and it is being dealt with. If the clinic funds that someone is selling the medication, we discharge the patients, because they do damage to the other more motivated patients in care.

Congressman SENSENBRENNER. But you know, as Chairman Rangel pointed out, every time a Member of Congress gets indicted, next weekend when we go home there's at least one of our constituents, and probably more, saying well, ha, ha, ha, that's what all of you guys do when you go to Washington. You all know that that isn't true. Thank you, Mr. Rangel.

The CHAIRMAN. Mr. Coughlin. We're joined by Nita Lowey, outstanding Representative from Westchester, we thank you for joining us.

Congressman COUGHLIN. Thank you, Mr. Chairman. While I realize the purpose of these hearings is methadone treatment but I can't have this panel of experts in front of me without asking about what appears to be the drug of choice cocaine and crack/cocaine. How do you and your institutions, first of all, treat crack/cocaine addiction, as opposed to heroin addiction? Second, just to follow up on a hearing we had in Florida, which indicated a multiple crack addicted births to the same woman, a woman who came in and delivered a crack addicted child and came back 9 months later and delivered another crack addicted child, any facts you have on multiple crack addicted births in your institutions?

Dr. NEWMAN. It's a horrendously difficult problem, certainly in New York, and in most cities around the United States. Nobody has any easy, sure-fire way to treat crack users, cocaine users. We certainly have nothing that can compare in terms of effectiveness with the impact of methadone maintenance on heroin use as demonstrated by the GAO. We do find that a surprising number of multiple users, heroin and cocaine users, when they are in treatment and receive services in a methadone program are able to give up cocaine as well as heroin. Certainly the number of cocaine users goes down, and that again is reflected in the GAO report. But there is no easy solution and one would hope that the federal government would marshall the resources necessary to help find some effective way to treat this terrible problem.

There has been in Florida a very widely publicized case of a woman who gave birth to a crack addicted baby and who was being prosecuted as a result. As I recall the news accounts, that same woman during pregnancy had applied for treatment and had been turned away because no treatment was available. That was in Florida, according to newspapers, but that problem certainly exists in this city as well. It has to be addressed, it has to be addressed by the Federal Government.

Congressman COUGHLIN. Do you have any figures on the number of multiple crack addicted births of the same woman?

Mr. PARRINO. There is no pharmacology that can intervene with cocaine or crack addiction. It doesn't exist at the present time. So at best, what all substance abuse treatment providers have to grapple with, is an extraordinary and awful problem of cocaine and crack use, and the best we can do is provide intensive counseling and hospitalization for the patient. If there is an individual who is continually using cocaine and crack, and we do the same things for individuals using alcohol as well, we hospitalize the patient, as best as we can, and follow up with intensive clinical services. Patient self-help groups at the clinic setting have also been helpful in this regard. In general, if there are counseling services provided at the site, and there are group counseling services as well, we have a much better opportunity to impact on the patients' cocaine or crack use. Results may not be seen in the first month or two, but as that patient remains in treatment and develops a relationship with the counselor, we become better able to impact on that particular drug of abuse.

I would join with my colleague, Dr. Newman, in asking that Federal research be funded to develop something to that effect.

Congressman COUGHLIN. Dr. John?

Dr. JOHN. I think one of the things that I, we are all saying, is that we started off as methadone maintenance treatment programs. At this point, we are methadone, crack, alcohol, AIDS, et cetera, et cetera, treatment programs. I think that in some sense one of the problems that we have is that we keep absorbing a number of society's problems in the methadone treatment modality, and I think under those conditions, we do get very stretched out. In our clinics I think the ratio of counselor to patient is 1 to 50.

The services we need to offer are so extensive that it is hard enough maintaining the service and we do counseling.

The CHAIRMAN. One to fifty?

Dr. JOHN. We do counseling even with these constraints.

The CHAIRMAN. Doesn't sound like counseling to me.

Dr. JOHN. Dr. Newman, what's your ratio at Beth Israel?

Dr. NEWMAN. Roughly 1 to 50, 1 to 60.

Dr. JOHN. One to fifty.

The CHAIRMAN. All right, it's hard for me to send my kid to a clinic knowing that a counselor has 49 other clients.

Mr. PARRINO. I agree. If I may interject something that is directly related to the financial resources they are going to be provided. I've been told by so many different government officials that treatment providers need to do more with less, that it's almost a perverse mantra.

The CHAIRMAN. After they finish questioning, I want to know at what point doctors have a responsibility not to talk about lack of resources when we're talking about life threatening services and I don't care whether it's in the emergency wards, in general hospitals, or methadone clinics. Lawyers can get away with that kind of talk, but doctors I think have a different standard than, "We didn't have money, therefore, we lost the patient." I'm sorry.

Dr. JOHN. I think we are saying that we do accomplish more with less. I think that what we're saying is that, we accept that responsibility. But it is also important to us to convey to you that the realities of methadone maintenance treatment reflect a number of problems for which we do need support. I don't think we are saying that we don't accept our responsibilities. We surely do accept our responsibilities though they are quite large.

Congressman COUGHLIN. Do you have any experience with multiple crack addicted births?

Dr. JOHN. I don't think that was in our experience. Multiple crack addicted births? We don't have any experience with that in the past, or at present.

Congressman COUGHLIN. Thank you, Dr. John.

The CHAIRMAN. Mr. Shays.

Congressman SHAYS. Thank you, Mr. Chairman. I just want to ask, and I don't need an answer if the answer is the positive one, that you all basically agree with the GAO analysis and recommendations? Let me put it this way, is there any area where you disagree?

Dr. **Newman**. Well, yes, I disagree with the conclusion that interim treatment as an alternative to no treatment at all should not be permitted. When the alternative is sending people who apply for help back to the streets to shoot dope, in a city where there are 200,000 addicts, and according to the State only 35,000 treatment slots, it's wrong to say it's better to do nothing. Yes, frankly, that is an area that I disagree with, in a report that otherwise is splendid in terms of the testimony that it presents for this treatment modality.

Congressman **Coughlin**. Do the other gentlemen agree that the interim program should be continued, then, where there is no backup?

Mr. **Parrino**. My position as the president of the Northeast Coalition, has been on record, not only at this hearing, but at the recently convened hearing of the National Institute on Drug Abuse and Food and Drug Administration, which convened in Bethesda, MD on February 28, that we are opposed to the use of interim care for the reasons that I stated in my abridged testimony——

Congressman **Coughlin**. I get the point, I get the point, I'm sorry. I don't mean to interrupt you, it's just that I do need to go. The point is, you don't agree? OK.

Dr. Drew I appreciate your bringing us back to the reality that we're talking about people who are suffering, and I mean that sincerely. I just wonder, Dr. Newman, if we go to the interim program, if that ultimately won't become the substitute, and that's my concern. In other words, if you guys don't call these things into question, then we're going to just see the easy way out by government, maybe the administration, maybe Congress allowing it to happen. Because I happen to believe that we're in this together, I think Congress allows the White House to do what it wants, and the White House allows Congress to do it, so, I'll state that.

Dr. **Newman**. Sir, I can't believe that that would happen. I know that for 20 years, 25 years, there has been a concern voiced by drug free programs that if you allow methadone maintenance to be introduced, which is much, much, less expensive, it will eliminate drug free programs. That debate is still going on internationally, right now. Yet, there isn't a country in the world where the more expensive drug-free programs have been driven out of business as a result of methadone being introduced. There's no way that I see that happening to comprehensive methadone, I don't think that Congress and I have enormous confidence in this committee's chairman and members would let it happen, and that's a battle that I would be right up front with you, because I agree it would be disaster.

Congressman **Coughlin**. I guess my point is there is no logical reason for a government to allow the interim program. The response and the logic is, if you're going to provide the program methadone, than you've got to provide the counseling with it. I don't see how we can allow it to be separated.

Dr. **Newman**. Sir, I would urge you keep in mind that there are a lot of people dying, dying, while we try to figure out how to expand the comprehensive services we both——

Congressman **Coughlin**. Let me ask you a question. Is it a question of not having money or is it not having the expertise?

Dr. NEWMAN. It's partially money, but it's also difficult to recruit staff and it is community opposition. As an administrator, I'm happy to get all the money you can give, but the fact is that I view money as one of the lesser constraints. Money won't overcome the terrible stigma against methadone treatment which adds to the community resistance despite the extraordinary findings of the GAO. Last night's televised attack on methadone treatment reflects a problem far greater than lack of funding.

Mr. PARRINO. The siting issue is an important one to focus on. I think it's how we got into the position we're in right now. As a result of the long-standing history of community opposition to drug treatment clinics, more patients got crammed into the existing facilities, we would not be talking about interim care as a possibility, if it weren't for that fact.

Congressman COUGHLIN. I need to understand that. In other words, we have less sites, and so each site handles more people?

Mr. PARRINO. That's correct. As a result, we have an incredibly constricted treatment system. Although the system itself is contained, I believe the whole concept of interim care floats to the surface because of the fact that treatment services aren't available and the treatment facilities haven't been able to open. No new treatment programs have opened in the city of New York in over 15 years.

Congressman COUGHLIN. Put them all in Charlie's district, that's what we do.

Dr. NEWMAN. But to the credit of the Food and Drug Administration and the National Institute on Drug Abuse, those two agencies are the only ones I know anywhere in the country and in any State in the country that have at least addressed the issue and are looking for an alternative. Except for those two agencies, and their proposal with regard to interim treatment, I haven't heard anyone even look for an alternative, let alone come up with one.

Congressman COUGHLIN. Let me just say this, because I am going to leave. Regretfully, I wish I could stay for the next panel, because I think it really is a terrific hearing, Mr. Chairman, that you've assembled and a complete package, and I'm missing that.

The CHAIRMAN. Well, you won't, because they're Washington-based, and I'm certain they'd be glad to come in with their revised testimony after this hearing. [Laughter.]

Congressman COUGHLIN. I'm not finished, let me just make this one point. I came here fully convinced that I don't want to see interim programs. I'm willing to say that 5 percent work well, and maybe it's because I realize that there's a lot to my understanding that's left out. But conceptually and theoretically, I just think it's a travesty to provide methadone and not provide the counseling. It seems to me, that if it's second best, like 5 percent, then it's 95 percent that shouldn't happen, and there's only a little bit of evidence that says maybe it should.

Dr. NEWMAN. But compared to staying on the street shooting dope, which is the only other alternative, to me it's 100 percent better.

Congressman COUGHLIN. OK, well, let me give you another option. The other option is that the interim is about half the cost, correct?

Dr. **Newman**. I don't even know what the exact cost is.

Congressman **Coughlin**. Well, I would like to know that. If we're talking about counseling and so on, are we saying it's $8,000 per year? No, it's a good question, what's the answer?

Mr. **Parrino**. The answer to the problem is a comprehensive treatment program, Mr. Webb talked about the fact that it's about $3,500 per patient, per annum, which is the rough average for New York State's treatment programs. From State to State it differs. In Massachusetts, it's $4,500, in Connecticut it's different.

Congressman **Coughlin**. What is it for the interim?

Mr. **Parrino**. I don't have the figures on interim.

Dr. **Newman**. I guess about $1,500, but money is not the main constraint on the expansion of the comprehensive program nor is money the rationale for interim treatment.

Congressman **Coughlin**. OK, but let's——

Dr. **Newman**. About $1,500.

Congressman **Coughlin**. I wish I didn't have to go, because it just strikes me that my instincts would tell me that if you could just even provide a more thorough program for half of the ones that you're providing interim, that they would be better off. Admittedly, you're just cutting yourself loose on some, and that's probably very thoughtless. Maybe Dr. Drew can comment?

Dr. **Drew**. I think those of us sitting around the table would all agree that under the best circumstances, that total treatment is the treatment modality of choice here, with counseling and social workers. That is what we would all like to see. But I would suggest to you, just one remarkable point. What happens, or what would have happened to those individuals who were on a waiting list who have had the opportunity to come to an interim clinic that I ran in the past 2 years? I personally identified patients with pressing problems, other than just their drug problem, at the time that they presented, such as active tuberculosis, they were unaware of, they just thought it was a cold, and some with hypertension, to the point of almost stroking, I diagnosed diabetes, infectious hepatitis. You see, the interim clinic, if the interim clinic concept is seen only as the patient/doctor interaction in terms of the treatment for drug addiction, then you are missing another valuable part of it——

[Pause.]

Dr. **Drew** [continuing]. In our community. We are trying to intercede earlier to reduce morbidity and mortality in individuals who may, themselves, may not even recognize the severity of the illness, other than their drug use.

Congressman **Shays**. Mr. Chairman, I just appreciate the contribution of our witnesses, I thank you very much.

The **Chairman**. Before we go to Congresswoman Lowey, if in any full package treatment center we have a ratio of 1 counselor to 50 patients, what is the doctor to patient ratio?

Dr. **Newman**. According to the rules, there's 1 full time physician for 300 patients. I believe that's the current ratio that's required.

The **Chairman**. Now, Dr. Drew, if in an interim program you're saying that that it's not just the addiction, it's the complexity of all these other health programs, and in the full program you have a one to three hundred physician/client ratio, how in God's name are you going to be able to deal with other problems other than addiction in an interim program?

Dr. DREW. Well, see, part of it is in the interim clinic, I am the detector of disease and I am the person who refers to the proper treatment facility, so that what I'm essentially saying is that in an interim clinic setting, it is not I who eventually controls the blood pressure, it is not I who gives the medication for tuberculosis, it's I who initially makes the diagnosis, and it is I who makes sure that that individual gets to the proper treatment modality.

The CHAIRMAN. Well, I think it is sad that our constituents can not receive that type of medical treatment unless they are addicted, so, I would agree with you that that is a service that is provided.

Now, Dr. John, believe me I understand that your center is a magnet for every problem that a poor community has and they come there to ease the pain, but what is the patient's relationship with this doctor? With these 300 patients, how often would a doctor see one of these people getting methadone?

Dr. JOHN. It depends on a number of factors.

The CHAIRMAN. Well, generally speaking, would you see a doctor at all, after you signed up?

Dr. JOHN. Well, absolutely, at least once a year, because we are in-effect primary care providers.

The CHAIRMAN. So, the doctors are writing prescriptions without even seeing the patient.

Dr. JOHN. Well, that isn't true.

The CHAIRMAN. Well, if they see the patient once a year and the patient is in the program for a year, then how does the patient get the substance, the methadone?

Dr. JOHN. The, Congressman, I say absolutely once a year, that is every patient gets a physical exam, once a year, but——

The CHAIRMAN. Listen, here's a hypothetical, I'm there, I want to do the right thing. You're the doctor, I've taken the exam and now I'm taking methadone. How often do you think I'm going to see you? I come in every day, every week.

Dr. JOHN. If you present problems——

The CHAIRMAN. My problem is nothing, I'm getting the methadone and I use it, I'm okay.

Dr. JOHN [continuing]. Without any additional medical complications, any medical problems otherwise?

The CHAIRMAN. Not that I want you to know about.

Dr. JOHN. We see you once a year.

The CHAIRMAN. Once a year?

Dr. JOHN. Once a year.

The CHAIRMAN. So, I can stay on my cocaine and get my methadone and everything's going to be all right between me and you.

Dr. JOHN. Mm, mm.

The CHAIRMAN. Who's going to stop me from taking it, the counselor——

Dr. JOHN. The counselor.

The CHAIRMAN. The 1 to 50 person?

Dr. JOHN. Uh, hum.

The CHAIRMAN. Now, how is he going to know if I'm on cocaine?

Dr. **John**. Because he will see you at least one time within a month, usually several times within a month.

The **Chairman**. I see. When he sees me how will he know whether I'm on cocaine or whether I've used the methadone?

Dr. **John**. OK, well urinalysis and observation.

The **Chairman**. Well, I understand that's a big problem.

Dr. **John**. It's a problem, we do them. The counselors talk with the patients, they develop relationships, and as they develop relationships, and as I said before, we do a lot with a little. Even though the ratio is 1 to 50, our counselors meet with their patients, and they talk with them, they develop an effective relationship, get to know them. The patients in methadone maintenance tend to stick around for a while.

The **Chairman**. Doctor, you're doing the best you can with what you have to work with. I want to get those papers on Beth Israel that relate to your contract you say forbids you to make a profit.

Dr. **Newman**. Yes; there is no way to make a profit under the State contract. I'd be delighted to send you the contract.

The **Chairman**. Why would you enter into a contract like that?

Dr. **Newman**. Sir, we have been providing healthcare services to a population that has been rejected by other healthcare providers, municipal as well as voluntary, for the last twenty five or more years. We are committed to providing service, and not to making profits.

The **Chairman**. Is that an unusual contract for a health provider to enter into?

Dr. **Newman**. No, sir; not at all.

The **Chairman**. Are most of our clinics and hospitals signing nonprofit contracts?

Dr. **Newman**. They do not make money on Medicaid or Medicare. Its regrettable, but if you look at the deficits of hospitals in New York City and New York state, you will see that they do not make money——

The **Chairman**. That's the hospital, generally, I did not know about the methadone contracts.

Dr. **Newman**. The methadone contracts are not intended to enrich the hospitals for providing a service and they are structured in such a way that they——

The **Chairman**. Listen, I'll be publicizing this, really, because I'm for profits.

Dr. **Newman**. I would be grateful.

The **Chairman**. I'm really——

Dr. **Newman**. I'll send you a copy of the contract, if you like.

[The contract appears on p. 309.]

The **Chairman**. Dr. Drew, your initial statement that you volunteered dealt with easing the pain, and you heard me talk about doctors that have come into my community selling drugs, over-prescribing drugs, and I don't know, they give away heating pads and they give away support hose, and I call them quacks. You know the people I'm talking about. There are long lines of addicts outside their doors—not to be confused with those doctors that see just poor folks—I mean, they just deal with addicted folks. But the more I listen to what you have to say, it reminds me of once when I talked with one of these people on the line and he says, "You know, Rangel, you're doing a good job, but I'm here to get my pain eased." I said, "Well, why do you come here?" He says, "Because I get my methadone in the morning, I get my wine in the afternoon, a little crack when I can get it, and these people help me to ease the pain, because I have to make it from day to day." I felt a little embarrassed trying to close down that mill, because even though the doctor was a rip-off artist, and the pharmacist who was next door to him clearly was criminal, Dr. Drew, weren't they too, easing the pain?

Dr. DREW. I think they were not easing the pain in accordance with ethical practices or the intent of the oath that we took. When I speak about this——

The CHAIRMAN. You say within?

Dr. DREW [continuing]. Within the intent of the oath that we took.

The CHAIRMAN. Do you think they were?

Dr. DREW. They were not.

The CHAIRMAN. Oh, OK. Well——

Mr. PARRINO. Maybe I can add something.

The CHAIRMAN. Do you know who I'm talking about?

Mr. PARRINO. I know precisely who you're talking about.

The CHAIRMAN. They're all over.

Mr. PARRINO. Yes, the reason I know precisely who you're talking about, is for 2 years I worked in developing quality assurance standards for the professional service review organization [PSRO]. I went to those particular sites in Harlem and I saw those particular doctors, and I was witness to all the cases that we worked up to get those doctors offices closed, but I think it's important to maintain a very clear distinction between those medication mills where doctors are prescribing psychotropic medications and well operated methadone treatment programs.

The CHAIRMAN. You're going to have to help us, because when the community says, "not in my backyard," they're talking about your clinics, and they're talking about these clinics, and they're talking about all of these people that these clinics attract because they have pain. So, if we had you people with, our people trying to close down those other people and increase the quality of care so that you don't have that ratio of 1 counselor to 50 patients and we would be able to bring back people that we have helped, we'd all be on the same team. You would be so far in the front of being identified against the things that we're talking about that no one could ever believe that interim care is worse than no care. The problem we're facing is whether or not interim care and the dispensing of methadone is contributing to a problem. You're saying, "Well, they could be out there shooting dope." There's no indication that they would not still be out there shooting dope, taking crack, selling methadone.

Dr. NEWMAN. They can't, according to the guidelines that have been proposed or suggested for interim treatment. If it's to be permitted, there would be zero, zero diversion, since there is no take home of any kind permitted by the guidelines as they have been proposed. So the diversion issue is not one to debate about interim treatment——

The CHAIRMAN. Well, what about multidrug abuse?

Dr. NEWMAN. That's a problem that we're trying to respond to.

The CHAIRMAN. OK.

Mr. PARRINO. I'm leaving this hearing very encouraged by your remarks, because now I can go to the State capitals in the northeast and say to the funding agencies, look, you've got to give us greater resources, we've got greater congressional and Federal oversight now, and we're promulgating better treatment standards——

The CHAIRMAN. I wouldn't depend on the Federal Government.

Mr. PARRINO. Well, somebody's got to provide the money.

The CHAIRMAN. I would not depend—you see the Federal Government is pushing money out to the local level and States in block grants saying, "We don't know what you're doing with it." If you were to ask the Federal Government today what is the Federal modality, what is the Federal plan for treatment, they would tell you, "We just got involved in this, we're looking at it." So, believe it or not, you guys are the national experts. That's why Dr. Prim is in Washington.

Dr. NEWMAN. I don't think that's——

The CHAIRMAN. We need some actual experts.

Dr. NEWMAN [continuing]. I don't think that's doing justice to the experts that are going to follow us on the next panel, sir.

The CHAIRMAN. That won't help your evaluation, doctor, but it's well said. They would tell you that they have no program, and if you wanted to stick around, that would be the first question. They have no Federal program. Accountability is brand new, just started under Dr. Sullivan. They just created the agency.

Mrs. Lowey.

Congresswoman LOWEY. Let me say this, Mr. Chairman, first of all I want to thank you for holding this very important hearing. I apologize to the panel and to you that because of another commitment in my district, I couldn't attend until now. I'm sure that a lot of the questions that I've had with the methadone program have been taken care of, and I don't want to keep reinventing the wheel. You look as if you've been through quite a few questions, Dr. Newman. I thank you all for being here.

Dr. NEWMAN. I watched a lot of TV last night.

Congresswoman LOWEY. But I just want you to know that we really want to get to the bottom of this, because I know that we all care about serving the people in our community. I have spent many, many hours visiting places like the Renaissance Project and, Phoenix House, treatment facilities which deal with the whole person. Unless we're going to deal with this type of counseling, unless we're going to deal with moving someone off drugs to a drug free life, we're not going to succeed in the fight against drugs. But, I know we have been discussing the fact that keeping someone from shooting drugs perhaps is an end in itself.

I look back at the hearing we had with the GAO several months ago, and all these programs were conceived with counseling, with the idea of moving these people back into the mainstream, back into the work force. Yet what we're hearing today is the interim solution probably has some worth in itself. What do you consider, Dr. Newman, as your guidelines for effectiveness. Perhaps, this was asked before, and if so, I apologize. No? Well, I'd like to know——

Dr. **Newman**. Sure.

Congresswoman **Lowey** [continuing]. What, based upon your programs when you were running them, how do you measure your own success?

Dr. **Newman**. First of all, according to the impact on the primary problems with which the patient has come to our program, and that is heroin addiction. That is a problem the patient has had for many, many years, the GAO report indicates that here in New York City, among the five programs that they reviewed here in this city, we are successful in 95 to 98 percent of these former hardcore heroin addicts within just 6 months of their entry into the program. I think that's phenomenal success.

We also measure success in terms of employment, in terms of reduced dependency on welfare, and we are able to show substantial reduction in criminality, substantial reduction in arrests. There are many criteria and for sure, we apply those criteria to our Beth Israel program. I'm sure this is true of others also, and we come out looking very well.

Congresswoman **Lowey**. Now, when they get off of heroin though, I understand that cocaine use has increased from 8 percent to 40 percent. Did they just switch from heroin to cocaine, or heroin to crack, and take their post in the street?

Dr. **Newman**. No, ma'am. They do not, Congresswoman. As a matter of fact the GAO report is an excellent indication of methadone treatment success in New York City. GAO indicates that between 60 and 90 percent of patients within 6 months of entering treatment are not using cocaine. Now, we know that virtually 100 percent are using cocaine at the time of admission. I would refer you to this really outstanding report by the GAO which indicates the dramatic effect of methadone, even in the realm of cocaine, although we have a lot more to do before we are satisfied with our impact. We can be really very satisfied with the effectiveness of methadone treatment on heroin use.

Congresswoman **Lowey**. But you're not happy, with the fact that cocaine use has gone up to 40 percent in the clinic. How do you deal with that, how do you justify that?

Dr. **Newman**. Congresswoman, it has not gone up to 40. Cocaine use goes down from nearly 100 percent at the time of admission to between 40 percent and 10 percent within 6 months. Treatment doesn't cause cocaine use. In at least 60 percent, and according to the GAO as much as 90 percent, of patients, cocaine use is eliminated. So, we do——

Congresswoman **Lowey**. I guess what I have trouble dealing with, is how can you justify the fact, whether it's gone from 100 to 40 percent, how can you justify the fact that people are coming into your clinic, getting their methadone, and 40 percent of them are still using cocaine.

Mr. **Parrino**. Right now, the mix of patients has changed. Twenty years ago there was a different heroin addict on the street. Today, there is a heroin addict that comes in using cocaine and alcohol. The heroin addict, in some regard, mirrors the fact that many people are out there using cocaine and alcohol in combination. Treatment programs have many difficult things to deal with. HIV infection has been talked about extensively. Increased patient morbidity as well. We take no solace in the fact that our patients are using or abusing cocaine. All we can do is prescribe the right dose of methadone which has a tremendous impact in decreasing heroin addiction. In fact, there's no other treatment modality in the entire United States that does it with that kind of precision. Criminality, is absolutely reduced.

The point is, that when we have people in treatment we then have the opportunity to deal with that cocaine use. The point, I'm making is basically that while it is true that a percentage of our patients continue to use other drugs, it is far better that they are in treatment because there has been a dramatic reduction in that drug use, not only in heroin, but in cocaine use.

Congresswoman LOWEY. What percentage of the patients do you think would be successful if we were able to combine the methadone program with real counseling? You're shaking your head, no.

Dr. NEWMAN. I'm shaking my head because not only do we provide counseling, we provide real counseling and, Congresswoman, we provide counseling that is tremendously effective, by people who are superbly motivated, and who are excellent at it. I was just shaking my head at the concept that there is real counseling in another type of program, but some kind of a sham in methadone programs. That's just not the case; we have wonderful counseling.

Congresswoman LOWEY. Let me say this, and again I apologize for not hearing most of the testimony today, but in the GAO hearing we had in Washington, it was very clear that of the centers we've visited, there was zero or maybe 2 percent success in counseling. It just didn't exist. So, perhaps there was additional evidence today, but when you're dealing with 50 to 1 that's pretty tough. I mean, with limited resources, we really have to make some tough decisions as to where the Federal dollars are going. When I see success in some programs, I just have to question whether programs that keep people on an alternate drug, makes sense if they're not really moving people off all kinds of drugs. Maybe maybe the justification is, and that's what I'm trying to get at, if I'm not making myself clear, maybe there's a certain kind of person who can't be moved off any kind of drug, and this is just sustenance, to sustain them on this.

Mr. PARRINO. Dr. John Ball's research indicates that if you take patients and forcibly discharge them from methadone treatment, better than 80 percent will return to heroin use within 1 year of leaving methadone treatment. That finding has been consistently reported over the past 25 years by a host of different researchers. It's a very important point to make, it's not an opinion, it's a fact. The issue of cost, which you bring up, is critical. I didn't create the standard of 50 to 1, that was once a Federal standard, it is no longer. Some States have the similar standards, other states have more stringent standards. As I mentioned before, there is a direct correlation between the investment that the entity makes, whether the entity is the Federal or a State government, into the treatment system and what we get out of the treatment system. The more available resources the better the outcome,

Congresswoman LOWEY. Our job is to figure out whether the resources that are being provided are being used as well as they could possibly be used. Another question before I turn it back to our Chairman. One of the problems I see with all the drug treatment modalities, no matter which ones you're looking at, is that the recruitment and the training of the counselors that are working with the addicts is not all it could be. This has been a major problem; not enough pay, people want to go into another field, et cetera. Can you give us some recommendations if you haven't already discussed it, concerning recruitment and training of your staff?

Mr. PARRINO. Well, one thing we do is upgrade employee benefits. But you've talked about that. A treatment program, as an employer, can only offer just so much to the potential employee, based on the available fiscal resources. We're trying to provide the best benefit packages. In terms of employee retention, we try to give the individual staff member a sense of being a part of the treatment program. We've found that with better and consistent training, employee retention improve.

Many of our staff haven't gotten significant salary increases over the last several years, in spite of the fact that they are exposed to a much more severely addicted and seriously ill population. Ultimately, no matter what training we provide, how much we improve the physical facility of the treatment environment, there are only so many factors that will induce a person to continue to work in a program if they're being paid at substandard salary levels.

Congresswoman LOWEY. What is the average length of stay, Dr. Newman, that you can keep one of your trained counselors?

Dr. NEWMAN. Trained counselors?

Congresswoman LOWEY. Yeah.

Dr. NEWMAN. Our counselors are with us, for the most part, for a very, very long period of time. I would say probably a quarter of our counselors have been with us for at least 15 years. Their dedication, their loyalty, their commitment to working with and helping the patients is on a scale that I have not seen in any other field of healthcare. It's really extraordinary. We have a very long-term group of staff people, and that's one of the reasons why our program is so successful.

Dr. JOHN. I would like to add that in our case, a very similar pattern exists.

Congresswoman LOWEY. That's interesting, because most of the centers that I visited complained about the fact that they're just finding it impossible to get people, and in Congress, we're looking at loan forgiveness programs for child care workers, for law enforcement people, and especially for drug treatment professionals.

Dr. NEWMAN. It's extremely difficult to recruit new staff, but the staff we do recruit, generally, are extremely well motivated, and stay.

Congresswoman LOWEY. Well, thank you very much, and I hope that we'll be able to continue the dialog. Thank you, Mr. Chairman.

The CHAIRMAN. If you have any statements that you would want to make for the record, we'll keep the record open for 10 days, as well as for anything you might want to add that time did not permit.

Again, I want to reiterate that those who are involved in trying to provide some type of treatment for the least powerful people that we have in our society, it does take a special degree of dedication to want to do that, and we really applaud those who have other choices but still want to provide this care, recognizing that methadone is only one of many modalities that can and should be used. There does come a time, when either for lack of resources or increases in population, doctors are going to have to make a decision, because of the burden and the lack of resources, as to whether or not these things become just supporters of drug addicts who don't want rehabilitation.

[Pause.]

The CHAIRMAN. There are people who enter in these programs to get methadone, not to get treatment, and if what we're saying is at some point, well, that's better than nothing, then we are going to have to examine that very carefully, because I don't know at what point, if you can't see the doctors, you can't see the counselors, if you can't see anybody, but somebody is there giving out the methadone, I don't know. But again, I hope that I have missed some papers that have been written by one or all of you or some organization that have failed to contact me to see what we are trying to do to force the Federal Government to talk about treatment on demand, but not some of this interim stuff that we're talking about.

Treatment means that you're going to provide the tools for someone to be productive. Sometimes it means to teach them how to read. God forbid our Secretary of Education should be involved in that type of a project, but you know, education is a part of rehabilitation. Hopefully, you're talking about getting people jobs and staying off of drugs, and I'd like to know more about what we're doing in those areas and which Members of Congress you're leaning on to do more so that I can join with them, to make certain that when people talk about doctors prescribing and overprescribing drugs without any direction or any concern for the patient you would know that's not happening, that they're not talking about you.

I want to join with you in that effort and to publicize it, and whenever you're ready, the committee's ready. Thank you for your patience.

The last panel is my old friend Bob Schuster, Director of the National Institute on Drug Abuse for the U.S. Department of Health and Human Services; a veteran in the war against drugs, Dr. Jerome Jaffe, Associate Director of the Office for Treatment Improvement; and Dr. Stuart Nightingale, who is the Associate Commissioner for Health Affairs, Federal Drug Administration, U.S. Department of Health and Human Services.

First, let me apologize for saying there was no Federal program when none of you had a microphone, but now that you do have the mic, I want to open and say that I know of no Federal program at all that I could feel free in recommending to anyone who had a substance abuse problem. I just wanted to say that in case you wanted to note that in your remarks. Your full statements, without objection, will be entered into the record. It's always good and enlightening to see you. We will start with Bob Schuster.

Dr. Schuster.

STATEMENTS OF CHARLES R. SCHUSTER, PH.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; JEROME JAFFE, M.D., ASSOCIATE DIRECTOR, OFFICE FOR TREATMENT IMPROVEMENT, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND STUART L. NIGHTINGALE, M.D., ASSOCIATE COMMISSIONER FOR HEALTH AFFAIRS, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. SCHUSTER. I don't know if this microphone is on, I'm not sure.

First of all, let me say that much of what I would have presented to you this morning has already been presented, and I don't want to be overly redundant. I would request that the full text of my presentation be entered in the record.

The CHAIRMAN. Without objection.

Dr. SCHUSTER. Thank you.

[The statement of Dr. Schuster appears on p. 312.]

Dr. SCHUSTER. First of all, let me say that I am very pleased at the hearing that has taken place here this morning. There is simply no question of the fact that all of our research has indicated that we need to improve our treatment. We need to improve the quality, unquestionably. We need to improve the currently existing treatment modalities as well as develop new treatment modalities for things such as crack/cocaine and other addictions for which we currently do not have really top notch, first class, effective treatment. There is just no question about it.

On the other hand, if there's any talk about the limited aspect of heroin addiction, which I would remind you is still affecting approximately 500,000 to 1 million people in this country, and which is associated with the spread of HIV infection, we do have an effective treatment: methadone maintenance treatment programs. I think that everything that has been said here this morning, has clearly demonstrated that. Further, Dr. McClellan's study that was presented here this morning by Dr. Woody, which incidentally was sponsored by the National Institute on Drug Abuse, compared three different levels of treatment: minimum methadone maintenance treatment, programs with standard care, and enhanced treatment programs.

The CHAIRMAN. I'm sorry, what study was this?

Dr. SCHUSTER. This was the study that Dr. Woody referred to earlier this morning.

The CHAIRMAN. I see, OK.

Dr. SCHUSTER. The study compared three levels of care. I should point out to you that this is part of a national effort to look at different treatment models in many different settings all across the United States. We are not only concerned with whether or not comprehensive treatment care is better than standard, we have to justify that it is even more cost effective. We are associating our clinical research studies with other health services studies, so that at the end of this time we will be able to say that although comprehensive care and enhanced care may cost more, it's effectiveness far outweighs the increased cost. That is the data that we need to be able to justify a policy of increase in the comprehensiveness of all treatment programs, not just methadone maintenance, but all of them.

The **Chairman**. Do you really think you need studies?

Dr. **Schuster**. Yes; we do and I'll tell you why. Comprehensive care is essential for some people. Standard care is just as adequate for some people, and minimum care works very well with others. For example, there are people that have families who are employed and who do not have significant psychological, educational, and social impairments. But they have gotten in trouble with heroin, or for that matter with another opiate, who do not need all of the services provided by a comprehensive treatment and rehabilitation program.

The **Chairman**. But if you go into a hospital that's a high-tech hospital, one of it's kind in the world, the fact that you went in with a headache and didn't need all those doctors, does not mean that it shouldn't be a comprehensive program.

Dr. **Schuster**. It should be available to you, is the point. What I am saying to you, sir, is that what we are studying is matching those clients to the level of treatment which they need. That's what our research is about, so that we can provide appropriate treatment in a cost effective fashion. Our resources, as you know better than I, are not unlimited, and we're trying to maximize the utilization of these, by a better matching of the level of treatment that is necessary to effectively intervene with the drug abuse problem of that individual. We are engaging in new studies in terms of how to better select clients and match them to different levels of treatment.

I will also point out to you that the issue of cocaine addiction is a very complicated one. It is true that we do not have any currently existing pharmacological treatment for cocaine addiction. As was pointed out earlier, in many cases the currently available behavioral techniques, counseling techniques, psychotherapy and other kinds of interventions, which go on also incidentally, in comprehensive methadone maintenance treatment programs, are very effective, at least for a certain percentage of cocaine users.

We also, however, are in what I would call almost a Manhattan project mode, in terms of attempting to develop other kinds of medications for helping people who are trying to abstain from crack use and cocaine use. We're not talking now about a methadone like drug. We're talking about a drug that would specifically decrease the kind of incredible craving and obsession which these people have when they are trying to abstain from drug use. We have some indications that there are such medications. There are studies now going on all over the United States and we're devoting $40 million to those studies right now. We have also gotten major pharmaceutical firms involved with us in a cooperative fashion to work on this project. I must say that this is the first time that the pharmaceutical companies have shown any interest in this and we're very pleased that they're working with us in a cooperative manner.

So, as you have always told me, Mr. Rangel, when I come here, I talk about the future. But this future is becoming closer and closer in terms of our ability to handle the crack/cocaine problem in a better fashion than we currently can.

I'd also like to say that we have developed a program this year for supervision of methadone maintenance treatment programs. This is a pilot program which was begun in October 1989 when we awarded a 2 year contract to the Research Triangle Institute in collaboration with the National Association of State Alcohol and Drug Abuse Directors. The objective of this project is to study the feasibility of establishing a performance oriented methadone treatment quality assurance system. This would monitor and aid in improving the quality and effectiveness of treatment provided by the 700 plus methadone maintenance treatment programs in the United States.

Essentially, what the system will do is this: when patients come in they will be assessed as to the severity of their problem, both their drug addiction problem and their other problems such as psychiatric problems, educational problems, social problems, et cetera. The kind of clients that they are dealing with would be used to rank that program. On a quarterly basis at a random period of time, urines would be collected at that treatment site, in order to determine whether or not there is methadone in their urine, as there should be; or whether or not other illicit drugs are being used, and this would be looked at in terms of the how long the person had been in the treatment program. So, we would have on a quarterly basis, a read out in terms of the effectiveness of that specific program. Poor quality would not result in closure of these programs but rather in the provision of technical assistance from the newly formed Office of Treatment Improvement, because their job is to provide technical assistance to programs that have deficiencies. This kind of monitoring program in conjunction with the technical assistance from OTI, will go a long way in assuring the quality of care provided by methadone maintenance treatment programs in the United States.

We are very pleased that we are doing this feasibility study, and if we can work this out, as I think we can, then we will push for this being mandated nationally. I'd like to point out that I don't think it should be restricted simply to methadone maintenance treatment programs. I know that the comment has been made that there are other treatment modalities, such as those provided in therapeutic communities and elsewhere. I think it's only fair to point out, that some of the very best therapeutic communities report retention rates of 10 to 20 percent. That's all. They only retained 10 to 20 percent of them. Now with those 10 to 20 percent that they retained, they do a very good job. But that has to be compared to methadone maintenance treatment programs where the retention rates of 6 months are sometimes as high as 75 to 80 percent. This is why I think it's very important that we evaluate all of the treatment programs in the United States, not just methadone maintenance. All treatment programs should be monitored and provide technical assistance if needed.

Finally, I'd like to say that in terms of the issue of diversion we are also working on that problem. We are looking for longer acting methadone like drugs which would allow the individual to be able to take the medication only once or twice a week, rather than having to come in on a daily basis. Although we want people to come in on a daily basis, all the in-treatment is counterproductive after they have achieved some degree of social rehabilitation and working may make it difficult for them to report daily. A longer acting methadone like medication would help to solve the problem of diversion. We have one of those types already. I hesitate to say, because it's been so long in coming, but I'll stake my professional reputation and say that we will have it out under compassionate treatment IND probably within the next 18 months. The second thing is, that we have a long acting depo-preparation of naltrexone. That will be into clinical testing next September. That's an antagonist strobe that would be implanted under the skin or injected under the skin and would prevent the individual from being able to get high on heroin for a minimum of 30 days. That means that the compliance problem with taking this antagonist would be minimized. We would only have to be in contact with the patient once every 30 days for that purpose. Obviously, we would also have to provide in those circumstances the other kinds of services which are essential for rehabilitation. So, I simply will end by saying that I'd be very pleased to answer any questions, but I want to emphasize the fact that we are all in agreement. Comprehensive methadone maintenance treatment programs are what we want. However, I think that it is fair to say that what prompted the FDA and NIDA to suggest interim methadone maintenance was perception that at least in certain sections of the country, there were people who were not being given a choice between interim methadone maintenance or bare-bones methadone, and comprehensive treatment; it was bare-bones methadone or nothing. As others have said before me, AIDS is a death penalty. There is no remittance from it. If you're infected with HIV you will die from that. I think that we really have to think through the fact that if a patient comes in and we have to wait a week before we can assign him to a treatment program, is it better to send them back onto the street where we know that they're going to be shooting up herion, or treat them with methadone which will not solve the problem, but will decrease the frequency with which they inject heroin Even decreasing it, if not completely stopping it, will diminish the opportunities for them to become infected or for them to spread the HIV infection to others if they are already infected. That is what we are attempting to deal with. We are very pleased at the amount of interest that has been shown in this and we, I can assure you, are taking all of the criticisms and comments that you and others have made into account in thinking this through. Thank you.

The CHAIRMAN. Thank you doctor, Dr. Jaffe.

Dr. JAFFE. We don't have a formal statement from O.T.I., but I'm here to answer questions, if I can, should issues touching upon O.T.I. come up.

The CHAIRMAN. Okay.

Dr. Nightingale.

STATEMENT OF DR. NIGHTINGALE

Dr. NIGHTINGALE. Yes, thank you, Mr. Chairman. I am Dr. Stuart Nightingale, Associate Commissioner for Health Affairs at FDA and I am accompanied by a Mr. Ross Laderman, who is Deputy Director of the Division of Scientific Investigations, Center for Drug Evaluation and Research, which has oversight of FDA's methadone maintenance program activities, and Mr. George Prager, who is an investigator in the FDA's New York District Office. I might add that Mr. Prager has over 15 years experience in inspecting for FDA and methadone programs.

[The statement of Dr. Nightingale appears on p. 321.]

Dr. NIGHTINGALE. We're here in response to your request to testify on the regulation of methadone maintenance as a treatment modality and especially the status of our joint FDA/NIDA methadone interim maintenance proposal. As you know, FDA shares responsibility with NIDA and DEA for regulating the use of methadone in narcotic addiction treatment programs. The FDA is responsible for ensuring that all programs using methadone are in compliance with FDA/NIDA treatment regulations for maintenance and detoxification. While DEA is expert in compliance with security and record keeping and other matters. Other authorities such as individual State authorities also apply requirements including preapproval requirements for methadone treatment programs. This is indeed a Federal/State partnership. We understand, in fact, that over 30 States with methadone programs have or are developing licensing and inspection compliance programs. More than 900 in-patient and out-patient methadone treatment programs are approved and are currently operating nationwide.

I'd like to say a word about the regulatory compliance, as this issue has come up so much already. During the period of the early and mid-1980's methadone compliance inspections were considered less of a priority and the agency limited inspections to so-called for-cause situations with severe compliance problems being ahead of them.

The CHAIRMAN. I didn't hear you, it was limited to what?

Dr. NIGHTINGALE. To so-called for-cause situations, in other words, FDA is notified that there may be a severe problem or problem with a particular program.

The CHAIRMAN. Notified by whom?

Dr. NIGHTINGALE. Well, it could be the States, it could--the DEA——

The CHAIRMAN. You would come in when you were notified by another agency?

Dr. NIGHTINGALE. For the most part, during those years. However, during that time most of the inspections were carried out by the State authorities, they were quite active at that time. Recently, however, FDA has redesigned this program to routinely perform surveillance compliance inspections of methadone treatment programs to assure compliance with the regulations.

This new program is due, in part, to the Anti-Drug Abuse Act of 1988, which authorized $5 million to be used to expand FDA's drug abuse activities, of which methadone is a major part. As a result, approximately 21 full-time equivalent positions were allocated to the FDA field offices with a considerable portion to be used to conduct additional methadone treatment program inspections.

FDA projected 498 inspections for fiscal year 1990. This is consistent with the agency's desires to inspect one-half of the existing methadone treatment programs during each fiscal year. The compliance inspection process is with—just a few words at this time—you have extensive descriptions of that in the prepared testimony.

The FDA compliance program guidance manual contains the policy and procedures for FDA monitoring of narcotic treatment programs to determine that the practices of these programs comply with the current regulations. The program provides for in-depth inspection of every approved methadone program as well as procedures for follow-up compliance activities on programs that are found with significant violations of FDA regulation. Our compliance actions include two types of post-inspection letters requiring corrective action. First, a written response by the program to be verified by FDA inspectors and, second, in the more severe cases, recommendations to DEA for suspension or revocation of the program registration.

I'd like to say a little bit about interagency cooperation. At the Federal level, interagency cooperation and coordination in conducting inspections and evaluating their results for followup actions, are not only encouraged but are institutionalized in program guidance, memoranda of understanding, one each with DEA and NIDA, and inter-agency agreements. We also have other forms that we use such as the Interagency Committee on Drug Control and the Methadone Treatment Policy Review Board to deal with policy issues as well as specific problems that might arise with programs. We are very concerned about diversion. The potential for diversion of methadone by patients has, indeed, been a concern since the inception of methadone maintenance programs that provide take home methadone.

There always has been this tension between take home medication as a rehabilitative tool versus concern about diversion of take-home medication. We certainly are acutely aware of the seriousness of diversion issues and problems surrounding methadone treatment programs, such as those announced in the article that you had been distributed with your letter and of course, the various other issues that have been raised. We, along with our counterpart agencies, are prepared to act quickly and to address thoroughly such problems. There is, indeed, after notification by DEA of their diversion problems found during the 1988 undercover intelligence probe. FDA, DEA representatives from the State conducted five joint inspections in August 1989. All of the programs inspected were notified of violations found, by letter, and have responded to us, outlining remedial actions. FDA has reviewed these and informed the programs that their actions are acceptable pending future on-site verification by FDA.

As I say, the issue of diversion is an ongoing one and there are a number of things that I think that can be done at the Federal, State, and local level, both in the treatment arena and in law enforcement to improve the situation. We certainly will be looking into those in the future.

I will not discuss the efficacy issue at this point, since that has been handled I think quite well, except to say that, we do believe that our compliance inspections for the regulations are part of the whole quality approach, and it's not only that there is compliance with our treatment standards, but it's also the whole issue of going into a program and discussing where the program may be failing, to adhere to the regulations. The preparations that programs go through knowing that they may be inspected and again, I think our more frequent inspections will help in this regard, as well, and other activities that even we, as a regulatory agency can do, such as distribution of information on how to improve the quality of programs, training course that we're going to put on for the FDA field inspectors, who can, I think, provide some technical assistance during the program site visit, as well as just compliance with the regulation. This indeed happens with other process-oriented compliance programs that FDA does have. We certainly will be looking along with NIDA at the possibility of incorporating any kind of performance oriented standards in the future, but this is not the current situation.

Now, I'd like to just say a few words about the interim proposal. This joint FDA/NIDA proposal was put forth as a good faith effort, by us, as a public health measure. It was based on the fact that there was a high rate of HIV infection and transmission among IV drug abusers. Amid reports of widespread treatment shortages in certain areas of the country, with long waiting lists to enter methadone treatment in certain areas. Measures such as interim maintenance were recommended in a report of the Presidential Commission on the HIV epidemic, as a temporary bridge, consists of treatment on demand until comprehensive treatment capacity could be expanded. Under our March 1989 proposal, the methadone would be dispensed on a temporary basis without the scope of the full scope of comprehensive support services: counseling, vocational rehabilitation, et cetera, that were required in the traditional comprehensive programs. We are very concerned, as Dr. Schuster says, about the entire HIV epidemic issue, particularly of importance is HIV infection in IV drug addicts, especially pregnant women and women of child bearing potential. We did feel this proposal, at least, would be a way to partially address that concern. The Beth Israel Medical Center had established a pilot project, it was under an IND at FDA for such a holding program while the patients were awaiting comprehensive treatment.

However, there had been other models over the years of the same kind of holding program approach on a temporary basis, and in a way part of the difficulty I think in articulating our proposal has been that it's almost an all or nothing situation, and if it's called methadone treatment, then why isn't it full treatment, and we can talk about that in a question and answer situation. It isn't really treatment in the more normal sense, it is meant to be a way of getting people who otherwise would be on the streets, not having any kind of therapy, really to have something, even though it's not the comprehensive methadone maintenance, and again, that has been said.

We received over 80 comments in response to our March 1989 proposal. Some commenter's suggested a public hearing or a meeting to address their concerns about the proposal, and on February 28, 1990 FDA and NIDA convened a public hearing. Twenty-three individuals, all organizations, testified at the public hearing. The Federal Register notice which announced the hearing detailed the issues and areas of concern identified in the comments to the proposal, and asked that data and evidence be presented that would address these topics. These issues included the nature and extent of waiting lists, the potential impact of interim maintenance on comprehensive methadone treatment, elements of the policy of transferring patients from interim maintenance to comprehensive treatment, polydrug abuse, and urine testing, all of the issues that we have heard a fair amount about today at this hearing. But, in particular in announcing the hearing, FDA and NIDA requested data and evidence on the impact of interim maintenance on treatment quality and on diversion and these, of course, are two central topics identified in your letter, and was the subject of much discussion today.

Dr. NIGHTINGALE. To allow no take home privileges, to patients in interim maintenance that diversion of methadone by this avenue would be nonexistent. A wide range of information and evidence was presented during the hearing both in support of and against the proposal. The administrative record for the hearing has only recently closed, that was on March 15. The agency's are presently consolidating and reviewing the comments that have been received. FDA and NIDA hope that the data and evidence presented during the hearing would help to resolve concerned raised about interim maintenance proposal and allow the two agencies to take a definitive step in one direction or the other. Of course, there are a number of different options, and we would be pleased to discuss this with you during the question and answer period. I should also add, along with Dr. Schuster, that we do value the opportunity to participate in this hearing and we certainly will find today's hearing, I've already found it of value, in our own deliberations as we look further at our proposal.

Thank you very much, Mr. Chairman, and other members of the committee, this concludes my summary comments, and my colleagues and I would be pleased to answer any questions that you might have.

The CHAIRMAN. Thank you Dr. Nightingale. I assume that the record is clear that the FDA is the new kid on the block in this war against drugs as it relates to methadone.

Dr. NIGHTINGALE. No; actually we were the first ones on the block in 1972, I think, was our first methadone regulation.

The CHAIRMAN. Have you been through——

Dr. NIGHTINGALE. Yes; IND investigation of new drug applications in the sixties for programs like Dr.——

The CHAIRMAN. What oversight has FDA provided over the last 20 years in the distribution of methadone?

Dr. NIGHTINGALE. Well, we've always had regulations governing treatment standards for——

The CHAIRMAN. What oversight of the regulations have you provided over the last 20 years?

Dr. NIGHTINGALE. We have provided varying degrees of oversight through on-site inspections over the years. There have been varying degrees of involvement depending on the resources essentially available to us, and we have worked close with the States, actually in the seventies and early eighties, contracted with the State agencies——

The CHAIRMAN. I see.

Dr. NIGHTINGALE [continuing]. That can carry out our inspections. We've been very much involved in——

The **Chairman**. So, most of what I may have seen happen with the State has been a result of a contract with the FDA?

Dr. **Nightingale**. No; not necessarily. I think at this point we have increased resources, thanks to the drug abuse act and the new FTE's and we hope to carry out these inspections ourselves. These are projected inspections and we may need more, I'm not——

The **Chairman**. Well, you mentioned NIDA and DEA and the General Accounting Office. Is it safe to say that, independently, the FDA has assumed an oversight responsibility for the distribution of methadone without waiting for anyone to ask you to look at something?

Dr. **Nightingale**. I would say it goes back, really, to the late sixties early seventies, where actually there always was, the predecessor of FDA, the BNDD, was active with us in the very first methadone programs that were licensed by the government, so it was always FDA, BNDD, DEA. NIDA hadn't been created in the early seventies, but well, it was created but——

The **Chairman**. With all the diversion problems that we've had, and DEA's been involved in helping us, you're saying that the FDA's been there giving assistance in prevention of diversion?

Dr. **Nightingale**. I'll turn it over to you, but I want to just deal with this. FDA has worked with DEA or its predecessor agency and NIDA since the very beginning when NIDA was created. The narcotic treatment act of 1974, vested HHS in the setting of treatment standards, NIDA and DEA have a memorandum of understanding and had a very close relationship since the mid-seventies on this whole program and it worked closely with DEA. But there had been varying degrees of activity, we even had a coordinated community, I mentioned this methadone treatment policy review board, was established by the Special Action Office of Drug Abuse Prevention under Dr. Jase Isegious, so the intent to coordinate all Federal activities both in standard setting and inspection goes back to the early seventies.

The **Chairman**. Which committee of the House has oversight over the FDA in this area? Would that be Energy and Commerce? Who provides oversight for your agency as it relates to methadone? Who provides money for your agency to expand your investigators for inspections in methadone?

Dr. **Nightingale**. We get appropriations through the Agriculture Committee for our activities. I would want to submit——

The **Chairman**. So, methadone distribution would come under Kika de la Garza?

Dr. **Nightingale**. I would want to submit for the record the exact——

The **Chairman**. That's what I thought it would be, Energy and Commerce, and it should be Waxman, right?

OK, Henry Waxman. Dr. Schuster, we've been going over this together for a number of years, and I assume that what we're saying now is that while there's good news down the line, that the best antagonist that we know for heroin addiction is methadone?

Dr. **Schuster**. No; that is not the case. We have other antagonist drugs——

The **Chairman**. That are now being used?

Dr. **Schuster**. Yes; they're being——

The **Chairman**. You have other clinics—what do you call those clinics?

Dr. **Schuster** [continuing]. They're not under the same Federal control, but about 10 percent of the heroin addicts in the United States are being treated with Naltrexone, which is a pure opiate antagonist.

The **Chairman**. Do we have any Federal clinics at all?

Dr. **Schuster**. Yes; Federal clinics prescribe that medication. But they are not——

The **Chairman**. They're not Federal clinics.

Dr. **Schuster** [continuing]. We don't have the oversight function——

The **Chairman**. We don't have a Federal program to——

Dr. **Schuster**. Yes; we have a Federal program in which the difference is that methadone has specific legislation that has given rise to regulations in terms of how it can be dispensed. Naltrexone can be dispensed by any physician in the United States who is licensed to prescribe a medication. So, it falls into a different category because of that. But the fact is, that many of our publicly funded treatment programs use Naltrexone, but we do not have the same oversight, because it doesn't have separate legislation——

The **Chairman**. Is the Federal Government treating State commissioners on how to handle drug addiction problems? I keep saying that there is no Federal program, and I'm waiting for someone to contradict me. Of course, now I am saying it again. There is no Federal program. There is no place for State commissioners to go. You can't go to the Secretary of Health. You can try what you want, you can refer to the Federal Government, but if you're looking for guidance and direction, our Government is looking to you. Don't you look to us. Now, that's what I say. What's wrong with that, Dr. Jaffe?

Dr. **Jaffe**. The State agencies get together they have extensive discussions, they meet reasonably——

The **Chairman**. I know they meet, I'm talking about, who tells them what's working, what's not working, what person, what name, what agency is taking advantage of the 25 years of experience that we've had as an addicted country, and feeding it out to these 50 heads of State addiction centers?

Dr. **Jaffe** [continuing]. Well, I think it's fair to say that much of the information——

The **Chairman**. Yes.

Dr. **Jaffe** [continuing]. Is not generated in or by the Federal Government, it is generated by a number of investigators conducting studies and those people publish. Also, there are very competent and very knowledgeable people heading these State agencies——

The **Chairman**. Who heads——

Dr. **Jaffe** [continuing]. Who need the information.

The **Chairman**. Who heads the group?

Dr. **Jaffe**. Who's been elected now, who's the: Chauncy Veatch, is the head——

The **Chairman**. No; wait. Let's try again—my Federal Government, OK?

Dr. **Jaffe**. OK.

The **Chairman**. Guy comes to me. He says, "I'm the State commissioner, I don't know up from down, what are you doing nationally," and I say, "I want you to see doctor—" fill in the name, "—because he really has an office and a staff that has been developing programs, and you tell them what you're going to do, they'll give you a quick evaluation." Whose office is that?

Dr. **Jaffe**. Dr. Kleber.

The **Chairman**. Dr. Kleber? What's his title?

Dr. **Jaffe**. He's the——

The **Chairman**. Dr. Primm just got to Washington, don't do that to me.

Dr. **Jaffe**. Well, you asked me, what would I say to you?

The **Chairman**. You mean all of this is brand new?

Dr. **Schuster**. No, no.

The **Chairman**. What was the old—listen, I've been down there for 20 years, so all I want to know is what have I been missing. Which group has had the responsibility in the Federal Government to coordinate, on a national level, drug rehabilitation programs, and what was the name of that individual or the names in the last decade?

Dr. **Schuster**. Up until 1981 it was the responsibility of the National Institute on Drug Abuse which was the lead Federal agency for, not only conducting research, but actually administering the treatment services which were publicly funded.

The **Chairman**. Then they got out of it?

Dr. **Schuster**. Yes; when the block grant went through. By virtue of the changes in the legislation that function was given to the States. The only function that remained within the Federal Government——

The **Chairman**. OK.

Dr. **Schuster** [continuing]. Was to continue to do research. Now, because of the 1988 Anti-Drug Abuse Act, they set aside a provision from the block grant. We now have the ability to collect data about what is going on through those State administered treatment programs, and we are collecting that data now in terms of what is going on and with what degree of effectiveness and so forth.

The **Chairman**. So, it's safe to say that for the last decade, there's been no accountability by the Federal Government at all, for all of the Federal dollars that have been going out there. I mean there just has been no Federal oversight or direction to any drug rehabilitation programs, except those that have been brought to the attention to FDA or DEA or——

Dr. **Schuster**. I would simply say that, as Dr. Jaffe said, the guidance that was given to the State agency heads was based upon what research we were conducting that would indicate what was new in treatment and what treatments were effective. But we were not getting feedback in any systematic way from the States, in terms of what was going on out there.

The **Chairman**. I'm going to resist going into the past. There's going to be an explosion of addicts, an explosion of treatment centers. It's going to be the growth industry, and regardless of whether my Government came into this screaming or yelling, they're in it now, and we're writing legislation so that Cabinet officials from time to time will have to report back to us.

Now, you mentioned, Dr. Schuster, different addicts need different levels of treatment and therefore, we're conducting studies in order to see which is the most effective. Now, it's been my experience, and also with—would Mitch Rosenthal agree with you about the retention rate for addicts on the the nonmethadone program?

Dr. SCHUSTER. Well, I would suggest that you look at the studies conducted by Dr. George DeLeone, who is employed by Phoenix House to conduct these studies.

The CHAIRMAN. I thought he was saying that for those who stay there *x* number of years, there is an 80- or 90-percent retention.

Dr. SCHUSTER. That's correct. That's correct, but if you talk about the number of people who enter treatment only about 15 percent stay——

The CHAIRMAN. OK.

Dr. SCHUSTER [continuing]. For the first 30 days. That's what I'm saying.

The CHAIRMAN. All right, I guess we're saying the same thing. Now, you were here for all of the testimony. Did you get the impression that a lot of these centers take in heroin addicts knowing that they don't want to be rehabilitated and put them on methadone programs?

Dr. SCHUSTER. I certainly didn't get that impression this morning.

The CHAIRMAN. Well, you know I kept pushing this theory and responses were coming that they're multidrug abusers, and it's better than being in the street, and——

Dr. SCHUSTER. Let me just point out one thing, sir. We have done very good studies in which people who are heroin addicts were referred by the court to come into our treatment programs. Those people, at the time that they terminated treatment, have done every bit as well as people who were so-called volunteers.

The CHAIRMAN. Aren't there career addicts who are on methadone programs and use heroin and other drugs and don't see counselors and don't see doctors?

Dr. SCHUSTER. No one here, I don't think, would defend that practice or attempt to say that methadone alone is a suitable solution to the problem of heroin addiction.

The CHAIRMAN. But doesn't it ease the pain in a sense? It reduces crime by subsidizing the illicit drug habit?

Dr. SCHUSTER. I would say to you, that if you had a pure heroin addict and you were to put him on an adequate dosage of methadone, you would decrease the frequency with which he took heroin. If their crime was related to their getting the money to obtain heroin, you would decrease crime. You would also be decreasing the frequency with which they would be sharing needles and spreading HIV infection if they're already infected.

The CHAIRMAN. Now, is that a part of the Federal strategy?

Dr. SCHUSTER. Certainly, we are concerned with the crime that is associated with drug addiction. Certainly, we're concerned with the spread of HIV infection, not only amongst IV drug users, but tragically from them to their sexual partners and to their children.

The CHAIRMAN. Doctor, you're giving me more answers of concern than I want. I'm trying to find out if the Federal Government supports access to programs that are designed for other than rehabilitation?

Dr. SCHUSTER. No.

The CHAIRMAN. OK. Now, the Federal Government's strategy is not to support the reduction of IV drug use and AIDS by putting people in interim programs. You're not saying that we've cut crime down because we cut down the heroin addiction so, therefore, we give them methadone, right?

Dr. SCHUSTER. Treatment is the most effective AIDS prevention strategy that we have. We, therefore, have outreach programs to encourage people to get into treatment.

The CHAIRMAN. Would I be a candidate with your approval, as a heroin addict to say, "I need some methadone to cut back on my heroin addiction because I don't want to catch AIDS?"

Dr. SCHUSTER. Yes.

The CHAIRMAN. OK, that's exactly what I'm getting at. So, we can start talking about methadone not for rehabilitation, but for AIDS prevention.

Dr. SCHUSTER. We can start talking about methadone treatment. Getting people to come in, perhaps for the first time, into a health service, at which time we will attempt to get them involved in the treatment process, involved in the——

The CHAIRMAN. So it's an inducement?

Dr. SCHUSTER. It could be.

The CHAIRMAN. It's like sterilized needles might be. Needles might be used to get people into treatment. You might say, We'll give you some needles to come in." That's another inducement, I mean possibly.

Dr. JAFFE. Mr. Chairman, we've had programs that have gone out on the street and given people coupons that they could redeem for $5, and what happens is, people who never came for treatment before, come and some stay. Now, the programs were there the whole time. I mean there are a lot of people there whose heads are foggy most of the time, who come in thinking maybe I'll just cut down. It's the task of competent and skilled people in the program to help them think that there's another alternative.

The CHAIRMAN. Dr. Jaffe——

Dr. JAFFE. Why can't we do that with all of them?

The CHAIRMAN [continuing]. Most people think that I'm violently opposed to distributing new sterile needles. My opposition was that the needles were the program, not an inducement to comprehensive programs, and I am inclined to believe that a lot of the full packaged methadone programs, are an absolute waste in terms of rehabilitation. They may do a lot in reduction of crime. They may do a lot in reduction of AIDS, and they may be one heck of a social service to provide. But in terms of providing the skills, the vocations, the support system, which I guess Dr. Schuster would call comprehensive, we don't find anybody doing that except the Rosenthal's and those type of residential therapeutic communities. We don't find that in the jails either. You put a guy in jail, you invest the money, but you don't provide the resources for that person to be able to come out and say, "I'm off drugs, I'm off crime, and I'm getting a job." Now, there may be some programs that you know about in my city. I am saying I don't know about them. When people are talking about interim care saying, "Well, it's better than nothing, it's interim, they're no slots," I want to find out where is the Federal Government's commitment to treatment and to have these things such as the $5, or the inducement to get people off the street, because ultimately we've made a commitment to full treatment. Will you explain to me what Dr. Newman meant with this no profit contract, too I had no idea. Do you know what he's talking about?

Dr. SCHUSTER. Dr. Jaffe, he would like to know what was meant by the no profit contracts.

The CHAIRMAN. I never heard of that.

Dr. NIGHTINGALE. Is it possible to get back to the, your last question?

The CHAIRMAN. Sure, sure.

Dr. NIGHTINGALE. I mean, methadone regulations and the interim proposal really are meant to deal with both the HIV epidemic and drug abuse, both to try to get people to enter treatment, and if you asked about a national policy the President's HIV Commission clearly recommended treatment on demand, the ability to get people into treatment programs. I think Dr. Drew earlier talked about just having a place where a person, instead of being on the street, can go and be referred to medical services. What can happen is identified——

The CHAIRMAN. I understand all that. My point was—I want Mrs. Lowey to question—that nobody has ever told me what the Federal Government means when they say treatment. I know what they mean when they say interim treatment, no frills treatment, inducement for treatment, but I don't know of any standard so that I can say, "Listen, I'm from the Federal Government, and your program doesn't meet this standard."

Dr. SCHUSTER. Well, let me say this. First of all, the Office of Treatment Improvement in conjunction with NIDA is currently developing what will ultimately be Federal Government precise standards.

The CHAIRMAN. OK, so we could then, it will have to——

Dr. SCHUSTER. Let me say that we have three principal criteria. First, that we have decreased drug use; second, that we have decreased criminality associated with it; and third, that we have increased pro-social behavior—having people employed, in school, or productively engaged in household activities. Those three criteria are what we have pushed for in all of our evaluations of treatment programs, not just crime, not just drugs, but work and pro-social behaviors as well.

The CHAIRMAN. Well, I don't know, I don't hear anyone in the Federal Government talking about getting people back into society as productive citizens. All I know is they want to feed them methadone or put them in jail.

Dr. SCHUSTER. I will send you all of the reports from the National——

The CHAIRMAN. Could you send the names of some of the clinics that the Federal Government is proud of and encouraging, so that I can take the committee there and be able to say something positive.

Mrs. Lowey.

Congresswoman **Lowey**. Thank you, Mr. Chairman. I wanted to address my question to you, Dr. Nightingale. Frankly, I was amazed, I didn't know that you were involved, and you were there since 1972, you've been with FDA?

Dr. **Nightingale**. Well, I was with the special action office with Dr. Jaffe in 1972.

Congresswoman **Lowey**. Could you give me an idea how many people are involved in the department in dealing with the diversion issue, across the country?

Dr. **Nightingale**. The diversion issue?

Congresswoman **Lowey**. The fact that we know that a lot of the methadone portions are being distributed and not being used in the appropriate manner.

Dr. **Nightingale**. OK, basically, as I said, ever since the beginning of methadone, when you have taken home you have the potential for diversion and it has been the problem with that issue has varied by region by city or by clinic, at various points in time. There has been a concerted effort to deal with this whether it arises as a problem that comes to the attention of either DEA or NIDA or FDA, and then local police, again, the discussion came up earlier. It's really the concern of law enforcement and treatment people. We could, and I mention the fact that there is a tension between treatment, rehabilitation, and the concern about diversion and you could cure the diversion problem completely, if you said there's no take home from any methadone program ever.

On the other hand, by doing that you'd be setting up a situation where, because a person had to come to the clinic 7 days a week or whatever, you would really be impeding any kind of relief from rehabilitation. So what we have, and it has shifted over the years, a shift in terms of what might be an appropriate schedule, depending on time in treatment that you could get take home medication, and certain rules and the regulations about what happens where there's a positive urine. Now, this brings me back to the point I wanted to make earlier that, indeed, there is a national treatment standard for methadone maintenance. There's a national treatment standard for methadone detoxification and it's, this is in regulation with specifics spelling out all these various components. It's pretty much unique in that it's the only treatment that I know of that exists in that format, indeed, it's the only medication that has prescribed by regulation how a physician should be using that in practice. So, it's a very unique closed distribution system which exists really under licensing of multiple agencies, including FDA and NIDA and DEA and the states.

Congresswoman **Lowey**. What I was getting at, and I think what concerns me, and my constituents is constant statements along the likes of, " we'll be looking in to them, we're concerned about diversion, we're consolidating, and reviewing, we're thinking about having discussions." This is 1990, the problems been around since 1972, you're consolidating, you're thinking about it, you're discussing. Has there been any progress in diversion, or 10 years from now, after new people are there and we're still consolidating and discussing, are we going to have the same problem?

Dr. **Nightingale**. I'd like to be a little bit more specific. Basically, I did use those terms, describing various things——

Congresswoman **Lowey**. It's not surprising, I've heard those terms used before.

Dr. **Nightingale** [continuing]. And, by the way, consolidating had to do with what we're doing with our agent program, and trying to develop a——

Congresswoman **Lowey**. But you're still trying to figure out how to deal with it.

Dr. **Nightingale** [continuing]. Now, as far as diversion is concerned I think we have been lax, I think Gene Haislip, in his testimony earlier, said that perhaps more should have been done there. I think we haven't utilized the full force of our interagency cooperation in this matter. I think that we haven't worked enough with local police, the DEA intelligence programs in the summer of 1988, I think, in point of fact, when DEA really came to FDA with this, the States had responsibility, and I think this was acknowledged earlier, I think we have to have a strategy in terms of dealing with abuses of diversion that are taking place outside of clinics. I think it has to have a much higher priority. I'll make it my business in terms of our coordinating activities that I'm responsible for to put this on a higher level. We should have routed strong letters to each of the program administrators in the methadone network and told them that there's a serious problem of diversion in certain areas and that this is threatening to undermine the credibility of the methadone treatment program. We should have done that.

Congresswoman **Lowey**. Have you ever written letters before?

Dr. **Nightingale**. Well, many years, well——

Congresswoman **Lowey**. I guess what I'm getting at, sir——

Dr. **Nightingale**. I think they had written letters in the past. I think States have been doing some of that as well. We have not tried to sit back and look at the totality of what's being done. I believe that is what is lacking at the present time. I think we do have a commitment, or we had a commitment——

[Pause.]

Dr. **Nightingale** [continuing]. FDA will do it, NIDA will do it, and I think we'll do it together, with DEA. I mean if we have to work more closely.

Congresswoman **Lowey**. I don't want to be pessimistic but, when we heard the GAO report, I understand that same report or a very similar report was released 10 years before that, so I guess what I'm getting at is what kind of hope can you give me? Because I'd like to believe that 5 years from now, we're still not going to be discussing and figuring out a way to deal with it. Is it resources, is it that you don't have enough inspectors out there, what do you really need, so we know that this problem will be dealt with?

Dr. **Nightingale**. I think there are two very distinct problems, but there is overlap. They're distinct in that when you talk about diversion outside a clinic where patients take-home methadone is being sold, you have a situation which is not usually scrutinized in the regular monitoring approach that takes place during an FDA inspection of a program. Even during a DEA routine inspection of a program, when you're looking at compliance with treatment standards, you're looking at security and recordkeeping issues. When we have sales and trafficking outside of the clinic, that is a different kind of a problem, it's a police problem, it's a law enforcement problem, it's a problem that action should be taken the people who are doing this should be arrested. They should be, if they're not, if they do this, in the face of what's happening, they should be taken off the program, if they're not being able to be rehabilitated, and that certainly is not part of rehabilitation. However, there is an overlapping area where the program managers who know this is going on, who are told what's going on outside their clinics, need to take those strong steps, to see that all counselors in the program advise their individual patients that this is a problem, that they're jeopardizing not only themselves, but also the program, particularly in the face of tremendous neighborhood opposition to methadone. So, I don't think it's been approached. I now it has not been approached in a vigorous way by all of our agencies, under the commitment that we're making now to do this immediately.

Congresswoman LOWEY. We'll remember that, even 1 year from now or 2 years from now.

Dr. NIGHTINGALE. I mention the fact that we now have increased FDA inspections which, I believe, will go a long way because of our increased resources actually directed to improving the quality of current standards as far as we're concerned and other scrutiny. The whole additional approach to research, particularly the part where the issues with NIDA are involved, is that we'll all be working together on it.

Congresswoman LOWEY. Well, Dr. Nightingale, I don't want to belabor the point, but let me just give you my own prejudices perhaps. I feel, and I agree with my Chairman, that if in fact methadone can be useful to us to keep people off heroin, to keep people who can't be in a Phoenix House, can't be in a Renaissance, can't be rehabilitated in a State where they can be producing and they can be part of our society, then I wonder why we're even dealing with taking it home, perhaps we should just keep it on-site.

Dr. NIGHTINGALE. You know, I think the problem is that somebody who has been on methadone for some period of time, is doing well, and wants to be employed, you can't tie them to the clinic on a daily basis. If you have an interim approach to try to get people into treatment and you're holding them there for some short period of time, you can make them come to the clinic every day indeed that shows a certain amount of motivation. So those are two different situations and part of what I said earlier, too, is a problem. We've had to give this, because of the regularity format, a term that is interim treatment, and I don't think any of us think that it's treatment in the real sense. It is meant to be a bridge to get people into the situation where they show through their responsibility and the regulation to deal with this, that they can be trusted to take the methadone and not sell it—to take it and use it. More has to be done in actually going and looking at the compliance with what happens with individual patients at the clinic level, as well, and I think we're in a much better position now to do that.

Congresswoman LOWEY. Based upon your statistics, and your information, what percentage of those take-home patients are diverting it and what percent are actually using it in the appropriate way, do you have any idea?

Dr. **Nightingale**. That has not been part of the inspection data that we gathered. We looked at random numbers of patient records from each clinic. Within those patients records we looked for problems that would be indicative of diversion. We want to make sure the clinic is following up on that problem. We don't take overall program statistics as to what percentage are in that category. We only know what percentage of the records we looked at might be in that category and the range depending upon the clinic from one or two out of ten, which is the normal amount we looked at, to sometimes as many as 10 out of 10, where the problem is not necessarily diversion, the problems with urine results which are not being followed up by the clinic. Some of which may be indicative of diversion.

Congresswoman **Lowey**. Well, Dr. Nightingale, I just want to say I look forward to hearing from you in a year or two when you mentioned you're going to pursue greater coordination among the different agencies to deal with this problem, which I understand is very serious in some of our communities.

Dr. **Nightingale**. Indeed, this will be a coordinated effort, certainly at the Federal level. These issues have to be dealt with at the local police law enforcement level as well. You can never eradicate the issue of diversion of a take-home dose by an individual patient. But, what we don't want to happen is have this methadone program closed, thereby depriving those who need treatment a place to get their treatment because of what several patients or more in a particular clinic have done. I think that's our objective.

Dr. **Jaffe**. I would like to make one comment: I do think it's important that you recognize that there are some things that are not fully resolvable within the existing technology. We don't have a drug that lasts for several days at a time. If you want the people to work—I can give the Chairman some examples where we got the Federal Government the Economic Development Agency to build an entire vocation education program for one of the programs here in New York—and to take care of their families, to pay taxes, you have to give them take-home medications. Given the technology that now exists—which is a drug that lasts at best, one day—it opens up the risk for some people to divert, no question. That problem will probably never be fully resolved, although, I think in most communities, it's fairly small.

One other issue that I don't think has been brought out, is what happens in a good clinic. People get to know their patients; they get to like them, they want to support them. If someone's been working for 2 years and, under some stress something happens and they use a drug once and then test positive, we can say no more take-home medication. In some cases that means no more job, no more mortgage, no more taking care of the kids, no more apartment. These are very tough decisions for clinicians to make. There will be times when the inspectors will find deficiencies because a positive wasn't acted on by taking away all privileges. Clinicians will break the rules because, in fact, one human being is dealing with another, and it's a tremendous amount of power that you have. When somebody is working every day and has been working for 6 months, finally taking care of the family, to say "now come in 7 days a week, because there was a positive" is very hard. Maybe it's even a mistake, because we can't afford to pay the $100 it costs us to do urine tests as we do on everybody in methadone programs. Tests in methadone programs are not usually verified with gas-chemotography or mass-spectrometry, so there are possibilities that, even the positive may be in error. Yet you have to deal with it. So, some things are irresolveable. I would not like to see programs closed down for such deficiencies any more than I would like to see programs such as Phoenix House or Daytop close down because, occasionally, somebody leaves when they're not supposed to and steals somebody's car in the neighborhood. That doesn't mean that the whole program doesn't work. That's one of the risks you have to take if you want to return some people to the main stream as functional citizens. I think you wouldn't feel that one person doing something bad in the neighborhood takes away from the 99 who do well in those programs that you're familiar with. I'm familiar with most of them and they all have their risks.

Congresswoman LOWEY. Certainly.

Dr. JAFFE. This diversion is one of the risks. I think the risk is relatively small, but I don't think it can be resolved next year or the year after until we have a different kind of technology, meaning a drug that can be given once a week, and that may be some years away.

Congresswoman LOWEY. Let me just say this. I know the Chairman and I, and certainly this committee, would not want to shut down any program that is assisting people, helping them work, helping them take care of their family and helping them move into society. I think our questions, certainly mine are, as a result of information which I've received that don't, frankly, back up those kinds of statements. That is our concern and with limited resources you certainly want to program those resources into situations where you really are helping people get back into society and taking care of their families.

Dr. JAFFE. There's some information you should know as you compare across programs. The first program that ever tried this was ours, in Illinois, let me give you two examples, we tried to randomly assign people who came in to therapeutic communities versus methadone versus hospital detoxification programs. It couldn't be accomplished because everybody we assigned to a therapeutic community simply did not accept the treatment, they just refused. There were people who wanted to get better, but not at that cost. When finally admitted to a methadone program, they did well. Now I've been in both of them, methadone and therapeutic and I participated in both of them; I have the greatest respect for all of these modalities, but not everybody sees themselves fitting into them, some people will fit in well to one and not in the other. One more small comment about waiting lists. Back in 1967 and Dr. Schuster was there at the time, we did a waiting list study, because we had a huge waiting list. We kept some people on the waiting list while we took people into regular treatment because we didn't want to overload our counselors. We kept track of what happened to those people on the waiting list, because we randomly admitted them. When we were ready to admit somebody because we expanded and could do so I got a letter from the brother of a young man on the waiting list who died of an overdose; that was the last time I was willing to put people randomly on a waiting list that needed the treatment. If I had put them on an interim care—which we didn't set up back then—I would have at least felt that when I got them into more comprehensive treatment they'd still be alive. As a physician, that made me feel bad, I fully understand Dr. Drew and Dr. Newman. I didn't even have to worry them that each dose might give them AIDS. I mean they could recover from an overdose, overdoses are not all fatal. But one dose of HIV and we don't have anything we can do with it. So there are a lot of issues here that have to deal with people who are working everyday, trying to get other people better. Having made those points, I think that they may——

Congresswoman LOWEY. I just want to——

Dr. JAFFE [continuing]. Give you some background.

Congresswoman LOWEY. I just wanted to thank you. Let me say that you are very persuasive and I think within any program, it's the person who's running the program that really is going to make the difference, and I want to thank all of you for your testimony. It's clear to me that you're very committed, and if this problem were easy, the Chairman wouldn't be heading the Select Committee on Narcotics for as long as he has. Together, hopefully, we can work on new solutions and continue to do what we can to eradicate the problem. I thank you very much.

The CHAIRMAN. Well, Doctor you're very persuasive in knocking down problems that I don't have. In other words, if you've got somebody who's working and taking home drugs and they make some mistakes in this diversion, we're not talking about that. Now, Mr. Prager, you're the investigator, right? You're the one who goes out in the street. Would you tell Dr. Jaffe that what we're talking about are people who are selling methadone in the street in front of the clinics? We're not talking about people who've made mistakes. We're talking about patients selling the methadone that's just been given to them, not even by the doctors, incidentally, just by somebody who is working at the clinic. The doctors only see them once a year, they say. So you're defending a program that nobody's attacking.

Dr. JAFFE. I'm not defending the programs you're attacking.

The CHAIRMAN. Well, you're talking about what I'm talking about and that is that it is wrong to have these people in the street selling methadone, and we know that nobody is doing anything about it, and when I say nobody, I mean, nobody. I mean everything we're talking about today is because we requested it. So, I don't know what role FDA has, but I understand whatever role you have, that you will take the initiatives to make certain that this is not happening in our streets, that's all.

Dr. NIGHTINGALE. I'd like to get back to that——

The CHAIRMAN. Sure.

Dr. NIGHTINGALE [continuing]. Specifically, as far as we're concerned. What goes on outside the clinic is a difficulty which involves more than law enforcement——

The CHAIRMAN. I'll tell you one thing, if heroin was in the street as a result of a doctor prescribing—let me back off here. Who is responsible for what doctors prescribe to patients who don't need it, is that you?

Dr. NIGHTINGALE. The State medical practice acts control all medications——

The CHAIRMAN. How about what Medicaid and Medicare——

Dr. NIGHTINGALE. If it's a controlled substance, then DEA is involved in terms of——

The CHAIRMAN. Well, how about these mind-altering drugs that you can get a prescription for from any doctor, is that a controlled substance?

Dr. NIGHTINGALE. These are controlled substances.

The CHAIRMAN. Well, this is what we have to do. We're going to have to arrange for a car ride around any districts that we're talking about, so that you can focus on what I'm talking about. Because what you are defending I defend. So, we don't have a problem there, now, it's happening in communities around the country, it's not just my congressional district, and we can't find anyone responsible for it. The DEA says that they have to act on pushers, the FDA I don't know, but we can't find any help from Health and Human Services. Everyone says the State has the responsibility, but I am telling you that we have doctors in our community who are overprescribing mind-altering drugs that the Federal Government is paying for. No one knows, no one can tell me who's responsible in terms of oversight.

Dr. NIGHTINGALE. I want to just add that FDA has a role in the labeling of these drugs, in terms of what's considered to be appropriate use.

The CHAIRMAN. These are pre-packaged drugs that are given to patients who are not examined, who get prescriptions that are signed by doctors who have not looked at them and that are dispensed by a pharmacist who is in the same shop. Now who would be responsible for that?

Dr. NIGHTINGALE. It sounds like, if they're controlled substances it would be DEA and then perhaps the State.

The CHAIRMAN. Well, OK——

Dr. NIGHTINGALE. We certainly would be pleased to assist in that——

The CHAIRMAN. We'll write the President of the United States and ask him whether or not he can determine the agencies or departments that are responsible for this. Also, I'm convinced that those who run the clinics know that outside of their clinics methadone is being sold. I know that. Now, you can tell me that the doctor's not responsible for violating State law, and I know that, too. But somehow—and you know, Mr. Prager, that you can walk to one of these places, and you know that the drugs that the people are getting inside they're selling it outside. They're not going to work, and the people who gave them the drug knew that they were unemployable. So I don't know what we're talking about. These people are drug addicts getting methadone and selling it to support their habits, and Dr. Jaffe's example of the hard-working couple that gets the seven doses for 7 days are not what we're talking about. We're talking about drug addicts receiving methadone legally to use it and they're selling it. They're not selling it after they get on the subway and see that they have a surplus. They can't wait to get out of the clinic. I don't even know whether they're selling it inside, but I do know they're selling it outside. I know everyone who works inside knows that they're selling it outside—people come there to buy it.

You know, when people walk away innocently and say, "My God you're attacking a good program," we're not attacking a good program, and when we talk about diversion we're not talking about a handful of people who got a week's supply and sold one or two of the vials. We're talking about a serious problem. Now, did you see a serious problem anywhere, Mr. Prager?

Mr. PRAGER. Mr. Chairman, during these inspections I've seen a lot of things taking place outside including someone shooting up behind my car, with government stickers.

The CHAIRMAN. You know what we're talking, you know the subject of this hearing?

Mr. PRAGER. They are selling in some cases, near the clinics, and I have seen it and in the instances where I've seen it, I've brought it up to the administrators, but I don't know the patients, and I have no way to identify the individual, except by description.

The CHAIRMAN. Where would you think the methadone came from?

Mr. PRAGER. I can, of course suspect that it came from the clinic, and that's why I bring it up.

The CHAIRMAN. That's pretty great. Now if that's the best we can get out of an investigator, you can imagine what we're getting out of the doctors. Here he sees the methadone, he sees the exchange of methadone and other drugs in front of a methadone clinic, and it's his strong suspicion that the methadone is coming out of the clinic.

Mr. PRAGER. Mr. Chairman, I don't turn and run, and the regulations I enforce stop at the door of the clinic.

The CHAIRMAN. OK.

Mr. PRAGER. I really——

The CHAIRMAN. What I'm talking about stops at everyone's door. There is nobody who really is responsible except my police, and they tell me, "Charlie, you're the guy bringing the methadone into the community, so you want me to arrest these sick people?"

Dr. NIGHTINGALE. I think in this case, it is a joint effort, even if it's not necessarily the regulatory effort of one agency, it's certainly the responsibility to pass the information on, and to try to see that some action is taken, and I think that's what we——

The CHAIRMAN. Dr. Nightingale, it's not going to happen that way, and the Federal Government ought to be put on notice that as we start thinking about expanding services, unless someone assumes the responsibility for at least saying that we're going to have tighter controls in what's going on, unless we can truly start talking about full treatment—not that everyone needs this type of treatment—that we're going to find communities rejecting what is happening in our communities. That is, we're merely setting up places for drug addicts to meet, to socialize, and to exchange different types of drugs. It's unfair because the doctors who testified on the previous panel are right in saying that they shouldn't be included in what's happening with that type of program. But as long as nobody is responsible for the policing of the programs that are federally supported, State supported, and city supported, I'm afraid constituents are not going to be sophisticated enough to distinguish between good programs and these clinics that certainly are the magnet for drug addicts, as well as the licensed doctors who no one seems to know anything about except that they're in every poor district and every minority district in the country. Yet, everyone tells me it's a local problem. Doctors who are reimbursed by Medicaid, not Medicare, Medicaid reimbursable, and everyone throws up their hands. FDA is in charge of the labeling, the DEA may be in charge of the drug, the General Accounting Office will look at it and study it, NIDA is out of it completely, Health and Human Services pays for it. The laws are being broken. and that's just about the size of it. You couldn't even suggest where I might go. I mean, I know you could, but [laughter] in terms of someone that you may have heard about in Washington—say, how about Bill Bennett? You think he might—no, response there either. Vice President Quayle? No. Well, anyway, as the problem grows and we ask the community to participate they're losing confidence in law enforcement, in politicians, certainly in providers, which your investigations clearly show, and unfortunately in government generally. When hearings conclude like this it makes it more difficult for us to measure what little progress we are trying to make.

Dr. SCHUSTER. I would only say, sir, speaking for myself, I am very concerned about the fragility of methadone maintenance treatment program. It has never enjoyed popularity I believe in it. Dr. Jaffe and I have been privileged to work with literally hundreds and thousands of patients using methadone with a great deal of effectiveness and sometimes we get a little bit passionate about it. We've attended the Christmas parties with their families, where they've told us, we have never been with people before in the past 15 years until they entered your treatment program. So, we feel very passionately about this, and we feel very passionately about the fact that people who break the standards of methadone maintenance care should be dealt with. We agree with you 100 percent. We certainly agree that anyone who is diverting methadone out into the street is violating the law. It's a schedule 2 substance and I would, whether they're addicted themselves and methadone——

The CHAIRMAN. What are we going to do about it? You want to protect a fragile program that's doing so much for so many, and I'm saying that whether we're just talking about a handful, they're in the street, we know where they are, and we can't find anybody, unless I ask for the entire General Accounting Office.

Dr. NIGHTINGALE. Well, I just wanted to add that I think that Mr. Webb from New York State made quite a commitment to really followup on this particular problem.

The CHAIRMAN. He's new you know. I had this other guy for 20 years and now I have this new man for 6 weeks to depend on him.

Dr. NIGHTINGALE. Also, I think we made a commitment at the Federal level, through the Methadone Policy Review Board, to look at this issue and to discuss how we can best deal with it, so we're not shrugging it off.

The CHAIRMAN. Are you new, too?

Dr. NIGHTINGALE. No.

The CHAIRMAN. The Methadone Policy Review Board, who's in charge of the Board?

Dr. NIGHTINGALE. Me.

The **Chairman**. Fantastic.

Dr. **Nightingale**. No; I will make a commitment to look into this with our sister Federal agencies.

The **Chairman**. Who's on the Board with you?

Dr. **Nightingale**. DEA, NIDA——

The **Chairman**. You're the chairman of the board?

Dr. **Nightingale**. Yes.

The **Chairman**. How long have you been chairman?

Dr. **Nightingale**. Well, actually I was appointed in 1973. [Laughter.] I've had several different seats since that time.

The **Chairman**. But you've been chairman all during this thing?

Dr. **Nightingale**. No, no, I'm not—I have not been.

The **Chairman**. When last have you been reappointed?

Dr. **Nightingale**. I was reappointed because of my past fine service. [Laughter.]

The **Chairman**. But when were you reappointed?

Dr. **Nightingale**. I's say about 6 months ago.

The **Chairman**. That's good enough.

Dr. **Nightingale**. I think this is a very important issue for that group to deal with and an appropriate forum for this kind of discussion. We're not passing the buck by saying, "It's not this agency, it's not that agency."

The **Chairman**. It's all right. Why don't you come visit me without the mics, without the hearing rooms, with Mr. Coughlin and interested members, and let's discuss what resources will be necessary. I mean this is what you should be fighting for. You Dr. Jaffe, can't allow all of those years you have invested in these programs to go down the tube just because he doesn't have the resources to excise those people that make the programs look bad. Working together, you tell me what you would need to monitor, and if we're losing the battle, at least we would know we fought one.

Dr. **Nightingale**. I certainly will take you up on that offer.

The **Chairman**. Now, would you know who the chairman is of doctors who overprescribe medicines to drug addicts, do you know what board would handle that, or the chairman——

Dr. **Nightingale**. I think it would be a State board.

The **Chairman**. No; I mean on the Federal level, the people who write the reimbursement, anybody from the audience might know.

Dr. **Nightingale**. I think it's part of that new agency created in the Public Health Service, the Healthcare Policy and Research Agency.

The **Chairman**. OK, well, listen. When you get back to Washington, this will be a great opportunity to improve the image of all modalities in drug rehab, and that is to chase out the crooked doctors who are taking advantage of the illness and taking Federal dollars who are not concerned at all about rehabilitation. Now, we're talking about hundreds of millions of dollars. You know that, are all of you familiar with what I'm talking about, because I'm taking the car——

[Pause.]

Dr. **Nightingale**. The methadone maintenance issue versus the other kind of mills that are going on that——

The **Chairman**. You want to know the connection?

Dr. **Nightingale**. Yes.

The CHAIRMAN. I'll tell you the connection. It's an easy one. You only have to live next to it to understand it doctor. You live on a block all of your life. All of a sudden, hundreds of addicts are lining up in the morning for treatment. Now, some are in front of the methadone clinics and others are in front of the mills. It's the same people. It's that simple. You need more, you want some more questions.

Dr. NIGHTINGALE. Well, I think we'd like to pursue that——

The CHAIRMAN. I'm telling you that these people are receiving legal drugs without examination with prescriptions that are already prepackaged for this particular group in every community that has an addict population.

Now, to someone who hasn't spent a quarter of a century in drug treatment, and they just look and see the addicts feeling better from whatever they're getting from a doctor, it's the same thing. There is no difference to the community person whether its from a methadone clinic or one of these Medicaid mills.

Yes, Dr. Jaffe?

Dr. JAFFE. Mr. Chairman, when I was in New York and I guess it's been about 10 years ago, I participated, I believe it was with the State's attorney, in prosecuting several of these Medicaid mills.

The CHAIRMAN. Exactly.

Dr. JAFFE. This issue was what constituted adequate diagnosis, what was appropriate for prescribing, whether the medications happen to be sedatives and antidepressants—probably the kind that you're talking about—they were being sold; prescribing was a sham. It was the job, I believe, of the States attorney, but I'd have to consult my notes to find out for whom I was an expert witness and for whom I testified at the time. But they did close these people down, and there was an agency in charge, I don't think it was Federal, however. I believe it was State.

The CHAIRMAN. I'm talking about 100-percent Medicaid reimbursable.

Dr. JAFFE. But Medicaid is, I believe, State regulated.

The CHAIRMAN. Well, it's——

Dr. JAFFE. Therefore, it becomes a State——

The CHAIRMAN. The Federal Government is in it, you know.

Dr. NIGHTINGALE. It's very possibly, the Inspector General is involved if there is fraud involving the Medicaid area.

The CHAIRMAN. OK, well.

Dr. NIGHTINGALE. We'll find out.

The CHAIRMAN. Listen, because you people are so dedicated, I hate to let my frustrations out on you, but I'm confident now that we have the new chairman for the oversight of methadone, which is a gift, and a new research panel to see who should have the oversight responsibility for Federal Medicaid programs that treat drug addicts and which are being abused. Like I said earlier, to the other panel, it may be that they're getting better treatment in these programs than in some of the authorized programs, because Dr. Drew said you gotta ease the pain, and I guess to a large extent, we're stopping IV drug abuse and a lot of other things—but it's legalization.

The record will remain open, I thank you for your dedication, I thank you for your testimony, and I do hope that we will be able to meet in Washington in an informal way to exchange information on how we both can do a better job, thank you.

[Whereupon, at 2:50 p.m., the committee recessed at the call of the chair.]

PREPARED STATEMENTS

OPENING STATEMENT OF

THE HONORABLE CHARLES B. RANGEL

CHAIRMAN

SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL

HEARING ON

METHADONE MAINTENANCE AND DRUG ADDICTION

U.S. COURT OF INTERNATIONAL TRADE

CEREMONIAL COURTROOM

NEW YORK CITY, NEW YORK

FRIDAY, MARCH 23, 1990

9:30 A.M.

GOOD MORNING.

THE HEARING WILL COME TO ORDER.

TODAY, THE SELECT NARCOTICS COMMITTEE CONTINUES ITS STUDY OF METHADONE AS A TREATMENT MODALITY FOR DRUG ADDICTION.

LAST AUGUST AT HEARINGS WE HELD ON DRUG TREATMENT, THE UNITED STATES GENERAL ACCOUNTING OFFICE ISSUED THE PRELIMINARY FINDINGS OF A STUDY IT IS CONDUCTING AT OUR REQUEST ON METHADONE MAINTENANCE. THESE FINDINGS SUGGESTED SERIOUS CONCERNS ABOUT THE EFFECTIVENESS OF CURRENT METHADONE PROGRAMS.

THE DRUG ENFORCEMENT ADMINISTRATION ALSO TESTIFIED ABOUT UNDERCOVER OPERATIONS IT HAD CONDUCTED IN NEW YORK CITY WHICH REVEALED SIGNIFICANT METHADONE DIVERSION AT A NUMBER OF CLINICS IN EVERY BOROUGH OF THE CITY. THE COMMITTEE LEARNED THAT SOME METHADONE PATIENTS WHO ARE GIVEN TAKE-HOME METHADONE DOSES BY THE CLINICS GO RIGHT OUTSIDE AND SELL IT, OFTEN TO BUY COCAINE, HEROIN AND OTHER DRUGS, WITHOUT ANY CONCERN THAT THEIR ACTIONS WILL AFFECT THEIR TAKE-HOME PRIVILEGES.

LAST MONTH, THE NEW YORK STATE DIVISION OF SUBSTANCE ABUSE SERVICES CONDUCTED SURPRISE INSPECTIONS OF SIX METHADONE CLINICS IN NEW YORK AND FOUND NUMEROUS DEFICIENCIES AT ALL LOCATIONS INCLUDING SIGNIFICANT METHADONE DIVERSION PROBLEMS AT TWO OF THE CLINICS.

WHAT MAKES OUR HEARING URGENT IS THAT, AT A TIME WHEN THERE ARE INCREASING CONCERNS ABOUT METHADONE MAINTENANCE PROGRAMS AND THE SECURITY OF THE METHADONE SUPPLY, THE ADMINISTRATION, THROUGH THE FOOD AND DRUG ADMINISTRATION AND THE NATIONAL INSTITUTE ON DRUG ABUSE, IS PROPOSING REGULATIONS TO MAKE METHADONE AVAILABLE TO PATIENTS WITHOUT EVEN THE COUNSELING OR SUPPORTING SERVICES NOW REQUIRED. THIS "MINIMUM MAINTENANCE" APPROACH OR "NO FRILLS" METHADONE AS IT IS SOMETIMES CALLED, BRINGS UP SERIOUS QUESTIONS ABOUT THE QUALITY OF TREATMENT TO BE PROVIDED.

IN ADDITION, THE "NO FRILLS" METHADONE PROPOSAL WOULD BE A RETREAT FROM THE DIRECTION WE MUST AIM TOWARD, NAMELY PROVIDING COMPREHENSIVE TREATMENT FOR ADDICTION. WE SHOULD NOT JUST BE PROVIDING ONE ADDICTIVE DRUG FOR ANOTHER. THE PROPOSED REGULATIONS APPEAR COUNTER TO THE ADMINISTRATION'S OWN DRUG STRATEGY WHICH EMPHASIZES IMPROVING TREATMENT QUALITY AND ACCOUNTABILITY AS MUCH AS, IF NOT MORE THAN, EXPANDING THE AVAILABILITY OF TREATMENT SERVICES.

TODAY, THE GENERAL ACCOUNTING OFFICE WILL ISSUE ITS FINAL REPORT ON THE EFFECTIVENESS AND OVERSIGHT OF METHADONE MAINTENANCE PROGRAMS. NEW YORK'S DIVISION OF SUBSTANCE ABUSE SERVICES WILL TESTIFY ABOUT ITS RECENT INSPECTIONS. THE FEDERAL DRUG ENFORCEMENT ADMINISTRATION WILL ANNOUNCE IMPORTANT ACTIONS IT IS TAKING TO REDUCE DIVERSION OF METHADONE TO THE ILLICIT MARKET. METHADONE EXPERTS, TREATMENT PROVIDERS AND FEDERAL

HEALTH OFFICIALS CHARGED WITH REGULATING METHADONE AND IMPROVING THE QUALITY OF TREATMENT WILL ALSO TESTIFY.

WE WILL BE ASKING SOME SERIOUS QUESTIONS TODAY.

ARE METHADONE PROGRAMS BEING RUN WITHOUT PROPER OVERSIGHT OR MONITORING? ARE SOME CLINICS SIMPLY A PLACE TO DISPENSE LEGAL NARCOTICS? WHY ARE WE SPENDING HUNDREDS OF MILLIONS OF DOLLARS ON METHADONE MAINTENANCE IF MANY ADDICTS ARE BEING ALLOWED TO SELL THEIR METHADONE SO THEY CAN BUY AND USE HEROIN, COCAINE, AND OTHER DRUGS? IS METHADONE MAINTENANCE IN ITS CURRENT FORM EFFECTIVE?

WHAT IS THE OVERALL GOAL OF MAINTENANCE? ARE WE TRYING TO HELP ADDICTS BECOME DRUG-FREE, INCLUDING FREE OF METHADONE? ARE WE TALKING ABOUT REHABILITATION, OR ARE WE ONLY TRYING TO CHEMICALLY ISOLATE AND REMOVE FROM SOCIETY PEOPLE WHO HAVE NO SKILLS AND NO HOPE OF GETTING OFF THEIR LEGAL ADDICTION TO METHADONE?

METHADONE IS NOT A PANACEA FOR HEROIN ADDICTION. IT IS DISTRESSING TO ME THAT OUR HHS SECRETARY, DR. SULLIVAN, IS PROPOSING "NO-FRILLS" METHADONE WHEN I HAVE NOT YET HEARD HIM SAY WHAT HE PLANS TO DO AT HIS DEPARTMENT TO ESTABLISH A COMPREHENSIVE APPROACH TO DRUG ABUSE TREATMENT AND PREVENTION. I AM CONVINCED THAT THE NEW INFORMATION TO BE PROVIDED AT OUR HEARING TODAY WILL PROVIDE STRONG REASONS TO WITHDRAW THOSE REGULATIONS AND MOVE TOWARD A MUCH NEEDED NATIONAL POLICY OF COMPREHENSIVE TREATMENT INSTEAD.

U.S. House of Representatives

Select Committee on
Narcotics Abuse and Control

Hearing on Methadone Maintenance

TESTIMONY

by

Arthur Y. Webb

Director
New York State
Division of Substance Abuse Services

March 23, 1990
New York City

Methadone, the drug used for detoxification and treatment of narcotic addiction, is daily dispensed in New York State to more than 35,000 persons.

That number represents nearly 70 per cent of all persons who are participants in the various drug treatment programs found in the system supported by the Division of Substance Abuse Services.

As time has progressed, this treatment modality has remained essentially unchanged for two decades even while the nature of drug abuse and drug abusers has changed dramatically.

"New" drugs have come into vogue. "Poly-drug" use along with a high rate of alcohol abuse characterize the abuser population. A market for "street methadone," illegally diverted from clinics, has arisen, bringing with it the problems of loitering and other drug trafficking to surrounding neighborhoods.

These and other problems that have come to be associated with methadone are widely known.

As the director of the state agency that finances, licenses and regulates these programs, I am extremely concerned about these problems and the impact they have on our communities.

At the same time, there is another side to this issue -- the treatment side.

We have more than 35,000 persons in New York who have sought treatment and who have chosen methadone as their way out of the all-consuming sway held on their lives by heroin addiction.

The methadone clientele is an aging one; many persons are in their mid-thirties or older. This is a population, too, that is not well, with a variety of ailments that include HIV infection and AIDS, tuberculosis and hepatitis. It is a group of people who, until they sought methadone treatment, had also remained under the best of circumstances outside of the health care network.

Thus, we have evolved a treatment modality that has achieved notoriety and unpopularity because of its various shortcomings and unwanted adverse consequences.

Meanwhile, it has grown to be the single largest drug treatment mode supported by New York State and represents, perhaps, the largest gateway for many thousands of persons from a life of drug addiction.

To examine methadone maintenance, and to help us all make some decisions about the direction we should be taking in this treatment program, we should first look at the problems.

In the drug world, everything has a market, everything has a price, everything has a value on the street.

In New York State, we have a unique street research unit -- the members of which include ex-addicts who have an intimate familiarity with the streets. Through them, I can tell you where you can obtain street methadone and how much it will cost you. These street researchers would also tell you that there will be many times when you will think you're getting methadone when you're not.

I'm sure, too, that you will hear from people at the Drug Enforcement Agency, who will tell you that they feel the problem has gotten so bad in some places that they have been compelled to take legal action.

For that matter, if you watched the NBC Nightly News last night, you would have seen an examination of the problem of diversion.

And, had you read the New York City daily newspapers in early February, you would have learned of the latest steps by the Division of Substance Abuse Services to attack the problem of diversion and the other perceived problems in the methadone treatment system.

On February 6, we conducted six simultaneous surprise inspections at methadone clinics in New York that we had previously identified as having problems. These unannounced visits -- not even those doing the inspections knew where they were going until the morning of the actions -- were comprehensive reviews that included an assessment of case records, medication administration, security, loitering, diversion, facility appearance and general safety. On-the-spot notices of deficiency were issued, requiring a plan of corrective action and a follow-up program.

Corrective plans have been received for each of the programs, which adequately address the problems that were cited. In the next few weeks, we will revisit each clinic to confirm that, in fact, the appropriate actions have taken place.

In line with our efforts to heighten compliance, methadone program review staff members have continued performing unannounced "notice-of-deficiency" reviews. In the coming weeks, we will reach each methadone program in New York City through this review process, which we will then extend to other parts of the State.

We are preparing a set of revised regulations that call for stricter standards and more-stringent minimum eligibility requirements for granting take-home privileges. Further, we are strengthening urine sample testing procedures to provide for increased test sensitivity for substance abuse. Confronting individuals with their illicit use may reduce that use and lessen the motivation to sell methadone in order to obtain cocaine and other drugs.

Clinics that continue to have severe loitering and diversion problems, and which remain unresponsive to the need to monitor and control those problems, will face the prospect of being closed.

In short, we know where the problems exist within our system and we are moving to do something about them.

Another issue before this committee is that of interim methadone maintenance treatment, a program that is currently being contemplated by the Food and Drug Administration and the National Institute of Drug abuse.

I do not favor such a concept as it has been put forth.

It is New York State's goal, and my goal, to provide a well-planned and comprehensive treatment strategy for each person coming to Division of Substance Abuse Services' programs. That is not what would be achieved by interim treatment clinics, which will put heroin addicts "on hold" with only daily doses of methadone and virtually no support systems until space is available in a more-complete program.

The people seeking methadone treatment have many medical problems; most are abusing cocaine, alcohol or psychotropics if not a combination of those substances in addition to heroin. Many have some sort of psychological or psychiatric impairment; many are homeless or with marginal living situations. Many are women of childbearing age, with their own special array of problems and needs.

The problems symptomatic of this group argue for a comprehensive approach if we are to impact on the many ills these persons have, including their addiction and the HIV infection risk. The intravenous heroin user, who is at a high risk for AIDS infection, requires a sophisticated level of care. Interim maintenance suggests the opposite: Minimal treatment, little in the way of adequate follow-up, minimum standards and low expectations.

Providing methadone without supportive services and absent a comprehensive approach runs counter to the high level of service provision we are seeking to achieve.

Who is getting methadone treatment?

In 1989, 30 per cent of those entering methadone maintenance treatment programs had not had any prior substance abuse treatment. These individuals are coming from the streets and from our jails -- they are persons who have remained outside our system for years. Innovative outreach and the fear of AIDS is bringing them to treatment.

Hispanics account for the largest percentage of those coming into treatment -- 38 per cent; 29 per cent are black and 32 per cent are white.

Clearly, studies over the past two decades have reflected the effectiveness of methadone in reducing drug use, particularly heroin, and in greatly reducing involvement in predatory crimes among those who have sought treatment.

Within each clinic, there is a medical component that provides base-line medical care, treatment for minor health problems and screening for communicable disease. With the high-risk for HIV infection associated with intravenous drug abuse, the methadone clinics have become the front-line position for the provision of primary medical care, as well as education and risk-reduction efforts directed both at the individual and at his or her family.

In effect, the methadone clinic has become the site for the delivery of medical services because the traditional medical system has shunned these individuals, or the ~~abuser~~ himself or herself has failed to seek care either being unaware of a medical condition or confronted by critical or hostile caregivers in the mainstream services.

I clearly recognize that there are great variations within the existing methadone treatment system in the adequacy and comprehensiveness of services.

That is why I see this particular modality as needing attention on two fronts:

Enforcement and service upgrading.

The Division of Substance Abuse Services has sent a clear and direct message to its methadone providers. We have embarked on a determined effort to heighten quality assurance and to clean up the problems associated with the program, even if it means weeding out clinics that cannot meet the standards we have set.

But, further than that, I have committed the agency to working with the providers on a major overhaul of the program to expand and improve the quality of care. We need to focus also on the physical plant needs of clinics, many of which are located in the poorest of buildings and which require an infusion of capital resources.

We need to recognize more than ever that methadone is the gateway into the broader treatment services for a large number of drug abusers. We must develop a comprehensive system of care and treatment that responds not just to their opiate addiction, but to their many other needs.

More-comprehensive health and social services are required in order to meet the many needs of methadone clients. For those who also abuse alcohol and other drugs, counseling and other rehabilitation services must be made available.

New York State and the Division of Substance Abuse Services are resolute in seeking to achieve the goals I have discussed.

At the same time, we could use some help from the federal government.

There ought to be a full review and evaluation of methadone programs, supported with federal funds, which would help all the states in revamping methadone treatment services.

Additionally, federal funds, specifically earmarked for methadone programs, should be made available so that we can concentrate on expansion of methadone-to-abstinence efforts as a key component of this treatment modality, and so that we can create new programs directed at services for women and children.

The Division of Substance Abuse Services stands ready to work with you in any way to achieve an upgrading of the quality of services and care in all drug treatment modalities.

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NEW YORK STATE • DIVISION OF SUBSTANCE ABUSE SERVICES

Mario M. Cuomo
Governor

Arthur Y. Webb
Director

February 26, 1990

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 4-62
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir or Madam:

The New York State Division of Substance Abuse Services (DSAS) has deep concerns about the pursuit of an interim methadone maintenance treatment program in the form currently contemplated by the Food and Drug Administration and the National Institute of Drug Abuse.

DSAS is a licenser, funder and regulator of methadone programs in New York State that treat on a given day some 35,000 persons.

This agency has recognized the need for a well-planned and comprehensive strategy to upgrade all modalities of drug treatment, to expand services and to develop innovative programs. The interim maintenance proposal to prescribe methadone without ancillary support services runs counter to the consistent and coordinated approach we are seeking to achieve.

From a clinical perspective, methadone itself has proven to be a valuable deterrent to drug craving. Once craving and drug use have stopped, however, the addict find himself or herself with few resources to combat the anxiety of dealing with the real world without drugs. It cannot be emphasized enough that cessation of drug use demands a dependable, professional involvement to encourage individuals to stay in treatment, to monitor their progress and to promote an alternative lifestyle to the one dominated by drug addiction.

The interim maintenance treatment scheme seems based on the belief that "something is better than nothing."

I do not subscribe to that belief.

The objective of drug abuse treatment is to reduce criminality, to reduce drug use and to redirect

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individuals to a positive life style. If the objective of the interim clinic is to put addicts "on hold" until a space in a comprehensive maintenance program is available -- based on the idea that something is better than nothing -- we are undermining the foundation of the treatment structure we have chosen to pursue before we have even attained it.

Methadone maintenance treatment is an extremely long process and the creation of "holding slots" will mean that individuals will obtain a "comprehensive slot" only if someone drops out or dies. The risk we run here is that we will put pressure on the treatment staff to push people out of treatment prematurely in order to give "a chance" to someone else. The greater risk is that this will result in a new "revolving door."

At a time when we are most concerned about the quality and effectiveness of treatment, a proposal to offer minimum service care with the hope of ultimate transfer to comprehensive methadone maintenance treatment would appear to be ill-conceived at best.

There are other significant issues related to the interim maintenance proposal that need to be addressed:

HIV Risk Reduction Benefits

Methadone maintenance treatment programs have responded over the years to the demands of an increasingly difficult and complex population. Dedicated staff and programs have operated under less-than-ideal conditions and with limited public support. And in the 1980s, the issue of AIDS further complicated the needs of intravenous drug users.

Specialized services have been integrated into the methadone maintenance treatment system. We are facing diseases that present unique challenges and require innovative treatment designs.

The intravenous drug abuser, who is at a high risk for AIDS infection, requires a sophisticated level of care. Interim maintenance suggests quite the opposite; its hallmarks are minimal treatment, little in the way of adequate follow-up, minimum standards and, unfortunately, low expectations. To make matters worse, this proposed, modified version of methadone maintenance treatment would occur at the entry point of treatment, where goals need to be established to provide the groundwork for long-term total rehabilitation.

The persons seeking methadone treatment are generally over 35, with five or more years of addiction history. They have many medical problems -- including AIDS, HIV infection and tuberculosis -- and most are abusing cocaine, alcohol or psychotropics, if not a combination of those substances, in addition to heroin. Many also have some sort of psychological or psychiatric impairment; many are homeless or with marginal living situations. Many are women of childbearing age, with their own special array of problems and needs.

The problems symptomatic of the group of persons seeking methadone treatment argue for a comprehensive approach if we are to impact on the many ills of these individuals, including their addiction and their HIV infection risk. Without this complete involvement, individuals will receive no therapeutic benefit and will ultimately leave treatment. The same holds true for those who are HIV positive and who are desperately in need of support and service coordination.

Waiting Lists

Congress has allocated funds to allow drug abuse treatment programs with demonstrated waiting lists to expand treatment, and this new funding surely will have a positive impact. It is extremely important to note, however, that dollars that have been allocated for waiting list reduction purposes are to expand comprehensive treatment approaches without compromising service delivery.

There has been much discussion about waiting lists for methadone treatment. The actual extent of such lists is, however, open to question, with a number of variables influencing the accuracy of reported information.

Unquestionably, there are programs that have waiting lists and clients in need. There are also programs that have open slots.

The merit of interim maintenance, nonetheless, should not be determined by the issue of waiting lists.

As an advocate for comprehensive quality care and coordination of services, I see the development of a centralized registry and referral mechanism as preferable to the unacceptable strategy of large-scale intervention with few or no support services. This would make better use of the existing structure without compromising quality services.

In addition, irrespective of the consideration of an interim maintenance rule, there should be a verification of waiting list numbers through the "single state agency." This needs to be done not only on an individual provider basis, but regionally as well, where there may be available space close to programs that are at or above capacity.

* * *

John Ball's research paper, "Reducing the Risk of AIDS through Methadone Maintenance Treatment," which was cited as a reference in your announcement, indicates effective methadone maintenance treatment programs can stop high risk behavior, but greater impact can be achieved by improved treatment.

We see drug addiction and AIDS as increasingly complex issues involving participation on all fronts over the long term. The notion of a quick-cure approach has serious, detrimental consequences that risk the dilution and fragmentation of the system of treatment.

I see no merit to the interim maintenance proposal as it has been put forth.

What we need to do, instead, is implement strategies that promote comprehensive and quality care for service recipients.

Sincerely,

Arthur Webb

Arthur Y. Webb
Director

United States General Accounting Office

GAO

Testimony

For Release
on Delivery
Expected at
9:30 a.m. EST
Friday
March 23, 1990

METHADONE MAINTENANCE: Some Treatment Program Are Not Effective; Greater Federal Oversight Needed

Statement of
Mark V. Nadel, Associate Director
for National and Public Health
Issues
Human Resources Division

Before the
Select Committee on Narcotics
Abuse and Control

SUMMARY

Heroin addiction is widespread in the United States. The National Institute on Drug Abuse (NIDA) estimates that there are 500,000 heroin addicts in this country.

Methadone maintenance is the most commonly used treatment for heroin addiction. In 1988, about 100,000 heroin addicts received methadone maintenance treatment at over 650 programs nationwide. These programs try to help addicts by combining methadone maintenance with counseling and other services.

Using the results of federally sponsored research and its own review of the activities of 24 methadone maintenance treatment programs, GAO found the following:

Program policies, goals, and practices differed. These program characteristics are set by the programs themselves and vary greatly.

Many programs are not effectively treating heroin addiction. A substantial percentage of patients continued to use heroin after 6 months of treatment.

None of the 24 programs evaluate their effectiveness. With one exception, the programs did not know the extent to which their treatment goals were met or the overall level of continued drug use in the programs.

Federal oversight of methadone maintenance treatment programs has been very limited since 1983. There are no federal treatment effectiveness standards for these programs. Instead, federal regulations have primarily established administrative requirements.

Interim maintenance, without other supportive services, is not effective. GAO concluded that interim maintenance--the provision of methadone without any counseling or rehabilitative services--would not significantly reduce heroin use.

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GAO recommends that the Secretary of Health and Human Services (1) develop performance standards for programs, (2) give guidance to programs regarding data collection so that NIDA can assess program performance, and (3) increase program oversight. GAO also recommends that the proposed interim maintenance regulations be withdrawn.

Mr. Chairman and Members of the Committee:

Mr. Chairman, I am pleased to be here today to discuss our report on methadone maintenance programs. The report resulted from your request concerning the extent of treatment services made available to methadone patients, and whether treatment programs have been successful in reducing heroin and other drug use among their patients. You also expressed concern over a recently proposed regulation that would allow methadone to be dispensed without the supportive services that are considered important components of effective treatment for heroin addiction. This proposed treatment is commonly referred to as "interim maintenance."

In response to your request, we reviewed the activities of 24 methadone maintenance treatment programs. These programs were located in eight states: California, Florida, Illinois, Maryland, New Jersey, New York, Texas, and Washington.

Using the results of federally sponsored research as well as our review of the 24 programs, we also assessed the potential effectiveness of the proposed interim maintenance program.

In summary, we found:

-- Many programs were not effectively treating heroin addiction. A substantial percentage of their patients continued to use heroin after 6 months of treatment. Patients also used other drugs, primarily cocaine.

- Treatment programs set their own goals, policies, and practices, which varied greatly. However, programs did not evaluate the effectiveness of their treatment and, therefore, did not know the extent to which their goals were met or the overall level of continued drug use in their programs.

- Just as program goals varied, we found great variation in the programs for the services they provided, their staffing levels, and the aftercare they provided.

- There are no federal performance standards, and federal oversight of methadone programs has been virtually nonexistent.

- Recent federally sponsored research found that interim maintenance would not significantly reduce IV heroin use and the corresponding risk of AIDS. GAO also did not find clear evidence of an overall serious shortage of methadone treatment slots that would justify interim maintenance.

BACKGROUND

There is no typical methadone maintenance treatment program. Programs can be found in rural and suburban areas as well as the inner cities, and may range in size from less than 100 patients to over 700. While most programs are established by private not-for-profit organizations, there are also private-for-profit and public programs.

Many private-for-profit programs do not receive public funding and charge their patients a fee for services. Publicly operated and private not-for-profit programs may receive public funds. These funds may be in the form of Medicaid, block grants, or other state and local government assistance. In the programs we visited, monthly revenue from all sources ranged from $145 to $533 per patient. Out-of-pocket costs to patients, which partially depend on ability to pay, ranged from no charge to $280 per month.

The Food and Drug Administration (FDA), National Institute on Drug Abuse (NIDA), and the Drug Enforcement Administration (DEA) share responsibility for regulating methadone maintenance treatment programs. FDA approves methadone maintenance treatment programs and has primary responsibility for ensuring programs comply with federal methadone maintenance regulations. NIDA is responsible for drug treatment evaluation and research. DEA authorizes programs and is responsible for ensuring that supplies of methadone are safeguarded against illegal diversion.

PROGRAM TREATMENT GOALS, POLICIES, AND RESULTS DIFFERED

Methadone maintenance treatment programs established their own goals, policies, and practices, which varied greatly. Program goals varied from treating only heroin addiction to treating abuses of all drugs with the eventual goal of getting the patient free of all drugs, including methadone. A wide variance also existed among program policies with respect to methadone dosage levels, urine testing, dismissing patients, and counselor staffing levels.

An adequate dose of methadone is necessary to stop heroin use. According to NIDA, 60 milligrams (mg) is generally the lowest effective dose, and low dose maintenance (20 to 40 mg) is considered "inappropriate." The average dose of methadone at 21 of the 24 programs we visited, however, was less than 60 mg.

Methadone maintenance can be an effective treatment for heroin addiction. But, judging from the continued use of heroin among patients, in practice, nearly half the programs we visited are not effective in treating heroin addiction. At 10 of the 24 programs, more than 20 percent of the patients continued to use heroin after

6 months of treatment. This is a higher percentage than experts believe should occur among patients in treatment.

At the 24 programs we visited, urine testing to determine the use of illicit drugs ranged from once a week to 8 times a year. At five New York programs, urine testing occurred once a week, but only one of the five programs observed the collection of urine in order to prevent a patient from tampering with the sample. A consequence of continued heroin or other drug use could be dismissal from a program. Fifteen of the programs dismissed patients for repeated drug use while nine did not.

Comprehensive services, including counseling and vocational training, have been found to be essential to program effectiveness and here, too, we found wide variation. Counseling is a key component of methadone maintenance treatment. Many counselors and program directors told us that it was difficult to provide more than minimal counseling to patients when a counselor's caseload exceeded 35 patients. Patient ratios at our programs ranged between 1 to 15 and 1 to 96. Research indicates that a good relationship between the counselor and the patient, which is developed over time, improves treatment outcomes. The average length of employment for counselors at the 20 programs that provided us data ranged from 6 months to over 8 years, but less than one-half the counselors had been employed for more than 1 year.

Most of the programs were lax in providing vocational and educational services, which are required by federal regulation. Few programs had such services on their premises and those that referred patients to services off-site did not track patient use or progress.

None of the methadone maintenance programs we visited evaluated the effectiveness of their treatment.

FEDERAL OVERSIGHT OF METHADONE MAINTENANCE VERY LIMITED

Federal regulations require that in order to use methadone in treatment, programs meet certain conditions such as requiring urine testing for continued drug use. FDA and NIDA have primary responsibility for regulating programs, but these agencies provided virtually no oversight of the programs between 1982 and early 1989. When FDA did begin inspecting programs for compliance with the administrative requirements of federal methadone maintenance regulations it found serious problems. FDA inspections in fiscal year 1989 found 62 programs that failed to (1) meet minimum urine testing requirements, standards for admissions, and medical evaluation requirements; (2) comply with frequency of attendance and take-home requirements; (3) maintain an adequate patient record system; (4) or meet minimum program standards. Thirty of the 62 programs were in New York.

Current regulations are process rather than results oriented. There are no federal treatment performance standards for methadone maintenance treatment programs such as the overall level, if any, of continued drug use that is permissible. Thus, oversight has been oriented towards regulatory compliance rather than program effectiveness.

EFFECTIVENESS OF INTERIM MAINTENANCE IS QUESTIONABLE

In March 1989, FDA and NIDA proposed revised methadone maintenance regulations to allow "interim maintenance"--the provision of methadone without any counseling or rehabilitative services. The purpose is to get addicts who are waiting for comprehensive treatment to reduce IV heroin use with its attendant risk of AIDS infection. The proposal is based on the assumption that many addicts are on waiting lists for treatment and that interim maintenance would result in reduced IV heroin use and the attendant risk of AIDS. Both assumptions, however, are questionable.

First, we found that while some programs had waiting lists, there is no clear evidence of a serious shortage of methadone treatment slots.

Second, a recent study by Department of Veterans Affairs (VA) and University of Pennsylvania researchers found that interim maintenance is not effective in reducing IV drug use. The VA researchers stated that ". . . methadone by itself does not guarantee clinical improvements or reduced AIDS risk." The report concluded that merely increasing the availability of methadone in the absence of administrative, counseling, and rehabilitative services may not adequately protect the majority of patients from continued drug use and the risk of AIDS.

RECOMMENDATIONS

In our report, we have made a number of recommendations to the Secretary of Health and Human Services. These include the development of performance standards, guidance for data collection on program performance, and increased program oversight. Additionally, we recommend that the interim maintenance proposal be withdrawn until there is sufficient evidence to clearly demonstrate its effectiveness in actually reducing intravenous heroin use.

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This concludes our prepared statement, Mr. Chairman, we would be pleased to answer any questions you may have.

Statement

of

Gene R. Haislip
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

before

the

Select Committee on Narcotics Abuse and Control
U.S. House of Representatives

concerning

Methadone Maintenance

on

March 23, 1990

New York, New York

Chairman Rangel and Members of the Select Committee on Narcotics Abuse and Control: I welcome this opportunity to appear before you again to discuss the issue of drug diversion associated with the dispensing of methadone from narcotic treatment programs (NTPs).

In my previous testimony on this subject, I reported the problems and concerns that the Drug Enforcement Administration (DEA) had with the operation of certain NTPs and how these clinics had become the source of diversion of methadone. We conducted an intelligence survey on the availability of methadone in the illicit market and the degree to which this availability could be associated with diversion from specific NTPs. This survey was conducted in New York City because it has a large number of NTPs and also because it accounts for approximately 50 percent of the national estimates of emergency room mentions for methadone reported to the Drug Abuse Warning Network (DAWN).

The results of our survey were most disturbing. Methadone was readily available in all five boroughs of New York, with an average selling price of $35 for 80 milligrams. Individuals were selling methadone with no fear that this action would have any effect on their ability to obtain more from the clinic. In fact, many were selling methadone in order to obtain money to buy other street drugs such as heroin, cocaine, or crack. Clearly the clinics which were dispensing methadone to these individuals were not monitoring their patients to insure that they were ingesting the methadone and that they were not using other drugs. In short, these clinics, which were supposed to be part of the solution to the drug problem, were instead sources of drugs for the illicit market on the streets of New York.

In view of the findings of this survey, we selected five NTPs in New York City for in-depth investigation. These investigations were conducted in cooperation with the Food and Drug Administration (FDA) and the New York State Bureau of Controlled Substances. The NTPs were selected for investigation based on documented evidence of illegal methadone sales by patients in the immediate area.

The violations that were uncovered at two of these NTPs during these investigations were serious enough to warrant the initiation of proceedings to revoke their DEA registration as Narcotic Treatment Programs on the basis that their continued registration was no longer in the public interest. The revocation of a DEA registration is an administrative procedure in which the registrant has the right to a formal hearing before an Administrative Law Judge. I have just signed the official notice to each of these clinics notifying them of the basis for the revocation action and informing them of their legal prerogatives. The successful revocation of the DEA registration of these clinics will force them to cease operation, as they would no longer be able to obtain, store, or dispense methadone.

Obviously, the closing of a narcotic treatment program is a serious action. However, after reviewing the operation of these clinics it is clear that their continued operation is not in the public interest. Outside of one of the clinics, 25 undercover purchases of methadone were made in a 4-hour period. Large groups of individuals were observed selling methadone outside of both clinics and some of these individuals told the undercover personnel that methadone was very easy to sell because they had plenty of regular customers.

The investigation of these clinics revealed serious violations, especially with regard to the operation of the program related to take home dosages. Based on the urinalysis records maintained by the clinics, it was shown that at one, 49 percent of the patients tested positive for cocaine use, 10 percent for a narcotic other than methadone, 1 percent for barbiturates, and 12 percent for other controlled substances.

In the second clinic, the results were similar: 50 percent of the patients tested positive for cocaine, 20 percent for various prescription drugs, and 5 percent for various opiates. Also, 1 percent of the patients had not ingested the methadone that was dispensed to them.

Despite these findings, patients were neither denied take-home privileges nor dismissed from the programs. Many other violations of FDA regulations were discovered, which included altering and backdating of records, dispensing of extended take-home dosages to ineligible patients, and deficiencies in the initial physical examinations given prior to dispensing methadone, including the failure to conduct urinalysis. This is, of course, only a partial listing of the violations which were uncovered. These regulations have been designed to insure that clinics provide comprehensive treatment services and not become dispensing centers for narcotics which merely exacerbate the neighborhood drug problem. However, this is precisely what has occurred in these and similar cases.

What have we learned from these investigations? It is clear that narcotic treatment programs which operate as these two have done accomplish nothing. They provide no incentive to the patient to stop abusing drugs. Quite to the contrary, they provide the patient with a steady supply of free methadone which he or she may sell or barter for other street drugs. The fact that the clinic will become aware of the patient's drug abuse through urinalysis is no threat since the status of the patient is not affected by the results of urinalysis. The clinics have simply become a source of drugs for the illicit market and have made a "laughing stock" of society's good will in providing the resources with which to operate such programs.

More importantly, it is not enough to merely say that these programs accomplish nothing. The negative impact of these programs on the community must be recognized. These programs have become a source of drugs for the illicit market. They make a travesty of their purported goal of drug treatment, doing a disservice both to their patients and to the taxpayer. Since their method of operation is obviously well-known at the street level, they may act to discourage individuals who are truly seeking treatment for drug abuse by leading them to believe all programs are operated ineffectively.

There may be many reasons why programs are operated in this manner. In some instances, it may be that the operators simply do not care for the welfare of their patients, but are only concerned with maintaining a high patient enrollment to insure maximum input of public funds. Others hide behind the concept of "treating the downtrodden" and choose to ignore the real effects of their activities on the people who come to them for assistance.

One factor that these operators have taken advantage of is that law enforcement has had to set priorities in enforcement activities because of resource problems. This has resulted in very little enforcement activity being directed towards the diversion of methadone from these clinics. This has created an atmosphere in which some clinic operators and their patients could abuse the public's trust with little threat of action being taken against them.

We are hopeful that this hearing and our discussion of the action that we are taking against these two clinics will place other clinic operators on notice that we will take all actions necessary to end this diversion problem. This is an area in which state licensing and regulatory authorities need to become more aggressive. I believe that it is also in the interest of all hardworking, dedicated treatment program managers to encourage and assist authorities in responding to this challenge to protect their own integrity. Finally, I would like to state forcefully that the legalized dispensing of drugs to drug abusers without rigorously controlled and thorough treatment objectives is no answer to the drug problem and simply adds to the illicit drug supply provided by the more conventional drug peddlers.

Mr. Chairman, this concludes my remarks. I will be pleased to answer any questions that you may have.

Statement of George E. Woody, M.D. at hearing on methadone maintenance, held by the Select Committee on Narcotics Abuse and Control, and held in New York City of Friday, March 23, 1990.

Introduction

I am pleased and honored to be asked to testify at this important hearing. I have followed the debates about the interim maintenance proposal that is currently under review by NIDA and the FDA. In this brief statement, I would like to provide the committee with an overall impression of these debates, and also respond to the specific items mentioned in Mr. Rangel's letter of March 14.

My overall impression is that the most important issues facing methadone treatment are being obscured by the debates on interim maintenance. I think that the important issues for methadone treatment are those of improving the ways it is delivered (as so well illustrated by the data of Dr. John Ball), of developing better treatments for cocaine abuse and dependence, of expanding the availability of good treatment programs, and of enrolling more addicts in treatment. This last point is especially important because there is evidence that the majority of people with substance use disorders, many of whom are engaging in behavior that puts them at high risk for infection by HIV, are not in treatment even when it is readily available. I do not see a strong emphasis on any of these points in the debates about interim methadone maintenance. I will return to these points after addressing the specific issues raised by Mr. Rangel.

Methadone Diversion

First is the concern sparked after the recent surprise inspections by the New York State Division of Substance Abuse Services showing significant diversion of methadone from maintenance clinics, and also by DAWN data showing that methadone ranks fourth among all drugs in hospital emergency room mentions in New York City. My impression from reading this data is that too many take-home doses are being dispensed in New York City.

Diversion of methadone from clinics takes place in two ways: 1) selling take-home doses, and 2) diversion at the pharmacy window. Of these two, selling take-home doses is the major culprit. Programs always struggle with this problem, trying to achieve a balance between control and providing the reward of less frequent attendance to those whose schedules make it difficult or impossible to attend the clinic on a daily basis, or who have demonstrated that they are making significant progress in rehabilitation. In some cases, take-home doses are absolutely necessary if a person is to work the hours demanded by some jobs or homemaking activities, and in other cases the person is so medically ill that daily attendance is inappropriate. There are many issues that arise in making clinical decisions about who should get "take-homes". But if the state inspectors find substantial diversion outside clinics, and if methadone is #4 in the DAWN data, the balance should be shifted immediately in the direction of fewer take-home doses.

The potential for diversion of take-homes doses is multiplied by the fact that a maintenance dose of methadone, because it is long-acting, will suppress clinically significant symptoms of narcotic withdrawal in some patients for as long as 36-48 hours. This can occur even though they may need the entire "blocking" dose (usually 60-80 mg/day) to adequately suppress heroin self-administration. This is probably true for a variety of complex reasons. Thus, some people who are receiving "take-homes" can skip a dose without experiencing serious withdrawal symptoms. Others, who know they cannot be comfortable if they skip the entire dose, may elect to take only a portion of the take-home dose and sell the remainder. Thus, a person receiving 3-4 take-home doses/week may divert methadone by selling either the entire dose, or only a portion, let's say half. If a patient is receiving 80 mg/day and sells half of 2 or 3 take-home doses for $1/milligram (the going rate in Philadelphia) he can earn an additional $80-$120/week. The extra money may be used to purchase drugs, or other items.

It is often impossible for clinic staff to know about this behavior unless someone tells them. Usually, patients who are selling take-homes will take other drugs and have positive urine tests. Staff can then discontinue take-home doses until the urine tests become "clean" for a period of time, say 3 months. If the clinic is taking urine tests only once/month, which is now the case in many locations, this behavior is likely to remain undetected for an extended time.

Diversion can be reduced quickly by simply reducing the total number of take-home doses. This must be done in a way that minimizes the chances for serious interference with essential aspects of rehabilitation. A suggestion for such a plan is as follows: 1) all clinics must be funded and open for operation 7 days/week (except holidays); 2) funding is available to perform urine tests on all patients at least once/week and for some twice/week; 3) as required currently, no patients are eligible for take-homes unless they have been on the program for three months or longer and show signs of progress in rehabilitation such as having urine tests that are free of unprescribed drugs; 4) the only patients eligible for take-homes are those who are working, in school, or unable to attend clinic daily due to homecare responsibilities (all conditions to be verified); 5) no person who meets the above eligibility requirements receives more than two take-homes /week unless they prove that they cannot come into clinic on the day(s) they request the additional take-homes; 6) all patients receive at least one randomly-collected, observed, urine test/week, and every person receiving more than one (or two) take home dose/week has two urine tests (exceptions are made for those with unusual circumstances such as very disabling medical conditions or irregular work schedules; the evidence for all exceptions is clearly documented; 7) patients who bring in a phony urine lose their take-homes immediately; 8) patients who have been in continuous successful treatment for five years or longer, including a very extended period during which they have produced "clean" urine tests, are given more lenient schedules, according to the best judgement of the clinicians; 9) two or more "dirty" urine tests within one month results in loss of take-homes; reinstitution will be considered after twelve continuously "clean" urine tests, spaced over at least one month, but preferably 3 months; 10) if not already available, begin using more of the long-acting version of methadone known as LAAM for consenting patients (it requires an IND).

Such a plan would probably reduce the amount of take-homes in the city from 30-50% of the total number of doses dispensed to about 15-20%. The major problem would be the difficult interactions between clinic staff and those patients who are having their take-home schedules reduced. This requires good clinical management and a lot of hard work, including advance notification of all patients by authoritative sources about what to expect, and why the proposed action is being taken. Having rearranged existing take-home schedules according to the above rules for 3-6 months, ask for another inspection and review the DAWN data or other appropriate public health information. Readjust the system according to how things are going, on a continuous basis. A quality assurance monitor for take-home compliance and diversion could even be established.

The second method of diversion is a matter of internal security by individual clinics. This form of diversion probably accounts for a small proportion of the overall problem, and all clinics are usually on guard to prevent it.

The point to be made from all of the above is simply that methadone diversion is a serious and ever-present danger that can undermine the credibility of methadone treatment. The major source of diversion comes from take-home doses. The amount of methadone dispensed for consumption outside the clinic must be monitored continuously, as are the patients who receive take-homes. Data indicating that significant diversion is occurring must be taken very seriously and corrective action must be taken. Public health and law enforcement agencies, in addition to clinical staff, can be very helpful in providing information about the amount of diversion that is taking place. It is probably impossible to eliminate diversion completely, but it can be well-controlled without harming the overall rehabilitation program by careful selection of patients, and by not providing any more take homes than are absolutely necessary to allow for participation in essential aspects of rehabilitation such as work and homecare.

Measuring Treatment Efficacy, Including Reduction in AIDS Risk Behavior

The second issue mentioned by Mr. Rangel is that of the efficacy of methadone treatment and how it is measured, including its effect on reducing AIDS risk behaviors. I understand that the Committee has heard previous testimony about studies which have demonstrated the efficacy of methadone. The early studies of Dole and Nyswander, the TOPS studies done by Research Triangle Institute, and the outcome studies of Sells et. al., McLellan et. al., Kleber et. al. and Ball et. al. and others provide overwhelming evidence for the efficacy of methadone in reducing opiate use and crime, and in improving the patient's chances for working and achieving a better overall adjustment. There is no data which indicates that maintenance treatment cures heroin addiction, though some individuals who have been treated with methadone have gone on to become drug-free for very extended periods of time.

All of the studies examining treatment outcome have their own methodologies, and each is described in the individual papers and reports. Generally, the studies use a combination of measures involving self-reports, technician-administered scales, and objective data such as urine tests and arrest records.

One measure that is being used widely in treatment outcome studies is the Addiction Severity Index (ASI). This is an interviewer-administered instrument that assesses the need for treatment in each of seven areas that are commonly affected in individuals with substance use disorders.

The areas assessed are: medical, drug, alcohol, family/social, legal, psychiatric and employment. The ASI can be administered in about 30 minutes by a trained technician. There is extensive reliability and validity data on the ASI. It has been translated into 12 languages (the Russians even used it on troops who became addicted to heroin in Afghanistan).

There have been a large number of instruments developed to assess behaviors that put one at risk for AIDS. The first wave of these measures was developed to address the special needs of homosexuals. Within the last several years, these instruments have been adapted for individuals with substance use disorders. This effort has been led by NIDA, which has developed a structured interview to assess high risk behavior. Two modifications of this interview have been used with success in a current NIDA-sponsored project being done at our research center. One is a self-report instrument and a second is an interviewer-administered version, which is more detailed. Copies of these instruments along with the ASI are included in the Appendix.

A strategy for assessing the efficacy of methadone treatment and its effect on reducing risky behavior is simply to use both the ASI, urine test results, and the NIDA risk assessment instrument in an appropriate study design. We are currently doing this in a project that aims to assess serostatus and associated risky behavior in heroin addicts who are both in and out of methadone treatment in Philadelphia. The results from the first set of assessments measuring drug use, needle-sharing, risky sexual behavior and serostatus among 371 methadone patients and a closely matched group of 98 heroin addicts who are out of treatment provides very strong evidence for the efficacy of methadone treatment in reducing both high risk behavior and HIV infection. Levels of drug use and unprotected sexual activity are between 3 and 10 times higher in the out-of-treatment sample than in the methadone maintained group. 16% of the out-of-treatment subjects are positive for HIV compared to 9% of the in-treatment subjects. These HIV infection rates are much lower than those in New York, probably because the virus was introduced at a later time in Philadelphia. Preliminary data from this study are included in the Appendix. Almost all differences in high risk behavior between the in- and out-of-treatment samples are statistically significant.

Similar results demonstrating the efficacy of methadone treatment in reducing AIDS risk and seropositivity rates have been found in New York by Dr. Kreek, by Dr. Vlahov in Baltimore, and by others. In summary, strong evidence is becoming available that methadone treatment is also effective in reducing risky behavior and HIV infection.

Comments on the Interim Methadone Maintenance Proposal

All of the studies done to date have assessed outcome from methadone treatment as it is currently structured. This includes paraprofessional counseling and other services, along with weekly urine testing, rules of conduct that are enforced by program staff, and other psychosocial aspects of the program. To the best of my knowledge, no studies have been published which have examined the outcome of dispensing methadone with no additional services. I understand that one is being done currently at Beth Israel under the auspices of Dr. Newman and his staff. I am not familiar with the specifics of the research protocol, but I understand that it is assessing a range of behaviors among those engaged in interim treatment, including drug use and high risk behavior, both at intake and at one or more followup points. The degree to which these behaviors are reduced by interim treatment, as compared to standard treatment and no treatment, is an empirical question that can be answered by a careful study of this modality.

We are currently engaged in a project whose aim is to determine the most effective levels of staffing patterns for methadone treatment. This project was stimulated by the interim maintenance proposal. The project is being done in two programs. The design calls for random assignment of new admissions and in-treatment patients to one of three treatment service levels: minimal counseling and urine testing (used only for research purposes and not to guide treatment decisions); standard treatment involving counseling with random urine testing that is used in treatment decisions, plus a few other services; and enriched treatment where patients have access to more social and medical services within the program than is ordinarily the case. This project does not compare an out-of-treatment group with an in-treatment group, but it does assess relative outcomes between these three levels of treatment.

Preliminary results show that a few patients in the minimal treatment condition are doing well, but that substantially more improvement is occurring in those who are receiving the other two levels of care. One unsettling finding has been that several individuals in standard treatment who were assigned to the minimal counseling group have lost some of the gains they made in the standard program. In fact, the majority of patients in the minimal services group have been switched to the standard treatment as a result of poor progress. Such action is necessary in order to remain in compliance with the requirements for protection of human subjects that was a condition for obtaining permission to perform the study.

These early data indicate that minimal treatment is substantially inferior to either of the other two treatment conditions. The study continues, and we will see if these early findings hold up when the sample size is increased, and when the average methadone dose is raised to 60-70 mg/day (it is currently around 50 mg/day). Thus, the data to date indicate that a few patients are doing well with minimal services, but that the majority are doing poorly. A copy of preliminary data from this study is included in the Appendix.

These results are intuitively sensible for a number of reasons. There is good evidence that narcotic addicts usually have many associated problems, including abuse or addiction to drugs in addition to heroin. The current most popular drug is cocaine, but benzodiazepines, amphetamines, alcohol and a range of others are commonly seen. One would not expect dispensing methadone alone to address these non-opiate drug problems. Other problems often include disturbances areas such as legal, psychiatric, medical, employment and family/social. The drug dependence is sometimes closely related to these associated problems, and progress in one or more of these areas can positively influence outcome of the drug problem, and vice-versa. Individual counseling, provision of social services, and medical and psychiatric treatments are often necessary if these additional problems are to be addressed. Currently, addicts have many new issues related to HIV infection, and thus drug treatment in general is becoming more complex.

My greatest problem with the interim maintenance proposal it that, within this framework of complexity, it seems counterproductive to become engaged in a debate about minimal services, especially if they are proposed as a national model. The available data, and the opinion of most treatment providers, indicate that most patients will do worse with minimal services than they do with those currently available. Studies also indicate that many methadone treatment programs, as they exist at present, could be substantially improved. Preliminary data from the project described above, and from other studies, indicates that more services generally produce better results. The emphasis should be on improving services and doing better, not on starting something that we have good reason to believe will be worse.

It seems that the major justifications for mimimal services are that they are less expensive, and the alternative is nothing at all. I do not disagree with the idea that minimal is better than nothing, at least for some patients, nor with the plan of allowing an interim program to operate in a location where that is the only choice. To the best of my knowledge, the Beth Israel programs are the only ones that have run out of treatment slots and are unable to expand existing services, and which have a substantial waiting list for methadone. This is certainly not true in Philadelphia. Thus, the immediate practical issue may have been solved already with the granting of an exception to Beth Israel to allow an interim program to operate. Data is also being gathered to examine the research issues raised by that program.

If possible, it might also be valuable to add a cost-effective component to this study. Expenses for interim treatment include rent, a pharmacist or nurse, security, probably a secretary and at least one counselor. A physician must also be hired to perform intake evaluations and write orders, and admitting labwork must be done. I am not certain how the cost of these services compares to those of standard treatment. Are they 10% cheaper or 50%, and how much is lost in efficacy for what savings? This is a difficult question, but some data about it may be possible to obtain.

As I understand the interim program at Beth Israel, there are no take-home doses, and patients are transferred to the standard program when a slot opens up. There is daily screening of patients by the pharmacist and a counselor so as to prevent someone from being medicated who is intoxicated with alcohol or other drugs, and to make the appropriate referral if a patient develops a medical or psychiatric emergency. These minimal services would seem necessary, if for no reason other than medicolegal concerns.

If consideration is given to approving interim treatment at another site, it might be a good idea to develop standards for a certificate of need for such a program. This would include some evaluation of the local situation and proof that the alternative to interim treatment is no treatment. Part of this evaluation might examine the economic demands that are sometimes placed upon patients who apply to public treatment programs. In our area, most of the public programs require some small amount of money, called "co-payment". Though minimal, some patients are so destitute or obstinate that they cannot or will not pay it, and are turned away. I am told that a similar situation exists in the Los Angeles area. Perhaps funds could be made available to existing publicly-funded programs which serve poor patients so that this barrier to treatment, which currently affects some applicants to methadone programs, is removed.

I see no point in applying the interim concept to privately-funded methadone programs, or to for-profit programs, as they appear to have adequate resources.

In summary, I strongly disagree with interim maintenance if it is to become a national strategy for delivering methadone treatment. This would clearly be a plan to deliver inferior care. It may have value under certain circumstances, and I think that these could be specified and made necessary requirements for licensing under a certificate of need. I am not aware of conditions that justify such programs at any place other than Beth Israel in New York. At this time, when there is popular support for more and better treatment for individuals with substance use disorders, and when AIDS is a real or potential disaster, especially among the poor living within large cities, it seems that we should take advantage of the opportunity to strive for better care and not worse. I guess that is what bothers me most about the debates on interim treatment. There is too much energy going into creating programs that are worse. Why can't we apply existing knowledge to make programs that are better?

Risk Assessment Project

Risk
Assessment
Project

Risk
Assessment
Project

Risk
Assessment
Project

Risk
Assessment
Project

6 MO

Date __________
Pt. ID__________

CONFIDENTIAL

1. What is your Age: ____
   Birthdate: ___/___/___

2. **Gender:**
   - ☐ Male
   - ☐ Female

3. **Race:**
   - ☐ Black/Not Latino
   - ☐ Black/Latino
   - ☐ White/Latino
   - ☐ White/Not Latino
   - ☐ Other: _________

4. What is your current marital status?
   - ☐ Single
   - ☐ Married
   - ☐ Separated
   - ☐ Divorced
   - ☐ Widowed

5. What is your current living situation?
   - ☐ Apartment
   - ☐ Own home.
   - ☐ Shelter.
   - ☐ Halfway house.
   - ☐ Room
   - ☐ On the Street
   - ☐ Other________________________

6. Do you live alone?

☐ Yes **GO TO QUESTION 8**

☐ No **GO TO QUESTION 7**

7. **IF you don't live alone,** how many people do you live with? ______

7a.Do you live with your husband or wife?
☐ Yes
☐ No

7b.Do you live with your sexual partner?
☐ Yes
☐ No

7c.Do you live with your parent or parents?
☐ Yes
☐ No

7d.Do you live with other relatives(Aunt/Uncle,Grandparents,Cousins,etc.)?
☐ Yes
☐ No

7e.Do you live with a friend or friends?
☐ Yes
☐ No

7f.Do any children live with you?
☐ Yes
☐ No

8. Did you have any children in the last six months?________

Education and Employment

9. Did you get a GED in the past six months?
☐ Yes
☐ No

10. Did you receive any other education or training in the past six months?
☐ Yes
☐ No 10a. **IF YES,** describe:____________________________

11. Are you employed now?
☐ Yes 11a. **IF YES,** what kind of work do you do:______________
☐ No ____

12. If you are not currently working, are you looking for work?
☐ Yes
☐ No
☐ I am working.

13. If you are not currently working, how badly do you want to work at this time?
☐ Not at all
☐ Slightly
☐ Moderately
☐ Considerably
☐ Extremely
☐ I am working.

14. How many months have you worked in the past six months?_______

15. What are your current sources of money (check all that apply)?

☐ Job (including part-time or under-the-table work)
☐ Spouse.
☐ Welfare (DPA)
☐ SSI (Disability)
☐ Unemployment Office
☐ Family/Friends
☐ Hustling
☐ Other ____________

16. About how much money do you get each month? $_______

17. Do you receive Food Stamps?
☐ Yes Value:$__________
☐ No

Drug and Alcohol

18. In the past six months, have you been treated for drug problems?

☐ Yes	18a. IF YES, what type of program was it?
☐ No	☐ Methadone
	☐ Residential program(Therapeutic community)
	☐ Outpatient drug-free counseling
	☐ Inpatient treatment(Hospital detox/rehab)
	☐ Other:____________________________

19. In the past six months, have you been treated for alcohol problems?
☐ Yes
☐ No

20. Do you feel you have an alcohol problem now?
☐ Yes
☐ No

21. **In the past six months, have you attended a Narcotics Anonymous (NA) meeting?**
    - ☐ Yes **IF YES,** how many times:_____
    - ☐ No

22. **In the past six months, have you attended an Alcoholics Anonymous (AA) meeting?**
    - ☐ Yes **IF YES,** how many times:_____
    - ☐ No

23. If you are now in treatment, what program do you attend?

    ☐ Giuffre Methadone Clinic
    ☐ Other:____________________
    ☐ Not in treatment

IF YOU ARE CURRENTLY ON A METHADONE PROGRAM:

24. What is your current methadone dose? _________mg/day
    - ☐ Don't know
    - ☐ Not on Methadone

25. Do you have take home privileges at this time?

    ☐ Yes
    ☐ No
    ☐ Not on Methadone

26. **In the past month, how often have you used cocaine and heroin together(Speedball)?**
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

27. In the past month, how often have you *injected* heroin(not mixed)?
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

28. In the past month, how often have you *snorted* heroin(not mixed)?
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

29. In the past month, how often have you *snorted* cocaine ?
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

30. In the past month, how often have you *injected* cocaine ?
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

31. In the past month, how often have you *smoked* freebase, rock, or crack cocaine ?
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

32. **In the past month, how often have you used speed/amphetamine?**
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

33. In the past month, how often have you used ice?
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

34. In the past month, how often have you used Xanax?
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

    34a. Is this prescribed by a doctor? ☐ Yes ☐ No

35. In the past month, how often have you used Valium?
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

    35a.Is this prescribed by a doctor? ☐ Yes ☐ No

36. **In the past month, how often have you used marijuana ?**
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

37. **In the past month, how often have you used beer,wine or liquor ?**
    - ☐ Everyday
    - ☐ A few times each week
    - ☐ A few times
    - ☐ Not at all

Arrest and Incarceration

38. Have you been arrested in the past six months?
☐ Yes **How many times:______What for:________________**
☐ No ______________________

39. Are you on parole or probation now?
☐ Yes ☐ City ☐ State ☐ Federal
☐ No

40. Have you been in jail in the past six months?
☐ Yes **How long?_____days_____weeks_____months**
☐ No

Medical Issues

41. Do you have any health problems at this time?
☐ Yes 41a.**IF YES**, what type of health problem(s)?__________
☐ No ____

42. In the past six months, have you stayed in the hospital overnight ?
☐ Yes **For what?___________________ How many days?_____**
☐ No

43. In the past six months, have you been treated in the Emergency Room?
☐ Yes **How many times?_____ For what?__________________**
☐ No

44. Please check those services that you have used to help you deal with your problems in the past six months:

a. ☐ Mental Health Center
b. ☐ Psychologist, Psychiatrist, Family Therapist or other therapy.
c. ☐ Public Health Clinic
d. ☐ Minister; Pastor; Priest; Rabbi
e. ☐ Planned Parenthood
f. ☐ Job Training Program
g. ☐ GED Program
h. ☐ College
i. ☐ Unemployment Office
j. ☐ Public Assistance (PA, Welfare, food stamps)
k. ☐ Veterans Administration (VA)
l. ☐ Women, Infants and Children Program (WIC)
m. ☐ Department of Human Services (DHS Caseworker)
n. ☐ Shelters
o. ☐ Women Against Abuse
p. ☐ Congresso
q. ☐ BEBASHI
r. ☐ Family Planning
s. ☐ Planned Parenthood
t. ☐ Other: ______________________
u. ☐ NONE

45. **In the past 6 months, have you injected drugs?**
☐ Yes
☐ No

46. **In the past six months, have you shared needles or works ?**
☐ Yes
☐ No

46a. **IF YES,** with how many different people did you share needles/works in the past six months? ________

47. **If you've shared needles** or works in the past **6 months, how many** times have you shared them: ___________
☐ Have not shared in past 6 months

48. In the past six months, have you **shared needles** with someone you knew (or later found out) had AIDS or was positive for the AIDS virus?
☐ Yes
☐ No
☐ Have not shared needles in the past 6 months

49. **Where** did you get your **needles** during the past six months?
_________________ ______________________________
_________________ ______________________________
☐ Have not used needles in the past 6 months

49a. During the past six months, about how many times did you use a needle before you got rid of it? ______________
☐ Have not used needles in the past 6 months

50. Have you been to a shooting gallery in the past 6 months ?
☐ Yes How many times?_________
☐ No

51. In the past six months, have you bought a needle in a shooting gallery?
☐ Yes
☐ No

52. Have you been to a Crack House in the past 6 months ?
☐ Yes How many times?______________
☐ No

53. In the past 6 months, how much of the time have you cleaned your needles and works before using them ?
☐ All the time, Every time
☐ Most of the time
☐ About half the time
☐ Less than half the time
☐ None of the time

54. If you have cleaned your needles and works in the past 6 months, how did you clean them? ________________________

55. When you didn't clean your needles and works in the past 6 months, why not?______________________________________

56. In the past six months, how many times have you used a needle after someone else without cleaning it?___________

57. In the past six months, how many times have you shared rinse water?_________

58. In the past six months, how many times have you shared a cooker?_________

59. In the past six months, how many times have you shared a cotton?__________

60. How would you describe yourself?
☐ Straight/Heterosexual
☐ Gay/Homosexual
☐ Bisexual

61. With how many different **men** have you had sex in the **past 6 months?**______

62. With how many different **women** have you had sex in the **past 6 months?**______

63. In the **past six months**, have you had sex so you could **get drugs**?
☐ Yes **How many times?**______________
☐ No

64. In the **past six months**, have you **given drugs** to someone so you could have sex with them?
☐ Yes **How many times?**______________
☐ No

65. In the **past six months**, were you **paid money** to have sex with someone?
☐ Yes **How many times?**______________
☐ No

66. In the **past six months**, did you **pay money** to have sex with someone?
☐ Yes **How many times?**______________
☐ No

67. In the past six months, have you had sex with someone you knew (or later found out) had AIDS or was positive for the AIDS virus?

☐ Yes
☐ No

68. **In the past six months,**how much of the time did you use **condoms** when you had sex ?

☐ All the time, Every time
☐ Most of the time
☐ About half the time
☐ Less than half the time
☐ None of the time

68a.Of those times you didn't use a condom during sex, what were some of your reasons for not using one?

____

____

69. How worried are you about getting AIDS ?

☐ Not at all
☐ Slightly
☐ Moderately
☐ Considerably
☐ Extremely

70. How worried are you that you may have already been exposed to the AIDS virus ?

☐ Not at all
☐ Slightly
☐ Moderately
☐ Considerably
☐ Extremely

71. Since your last blood test with us, have you had a blood test for the AIDS virus (HIV) any place else in the past six months?

☐ Yes 115a. Where were you tested?____________________

____

☐ No

INSTRUCTIONS

Below is a list of problems and complaints that people sometimes have. Please read each one carefully and circle the number that best describes how much you were bothered by that problem during the past week. Please choose only ONE.

For the past week, HOW MUCH WERE YOU BOTHERED BY:	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Headaches	0	1	2	3	4
2. Nervousness or shakiness inside	0	1	2	3	4
3. Unwanted thoughts, words, or ideas that won't leave your mind	0	1	2	3	4
4. Faintness or dizziness	0	1	2	3	4
5. Loss of sexual interest or pleasure	0	1	2	3	4
6. Feeling critical of others	0	1	2	3	4
7. The idea that someone else can control your thoughts	0	1	2	3	4
8. Feeling others are to blame for most of your troubles	0	1	2	3	4
9. Trouble remembering things	0	1	2	3	4
10. Worried about sloppiness or carelessness	0	1	2	3	4
11. Feeling easily annoyed or irritated	0	1	2	3	4
12. Pains in heart or chest	0	1	2	3	4
13. Feeling afraid in open spaces or on the streets	0	1	2	3	4
14. Feeling low in energy or slowed down	0	1	2	3	4
15. Thoughts of ending your life	0	1	2	3	4
16. Hearing words that others do not hear	0	1	2	3	4

For the past week, HOW MUCH WERE YOU BOTHERED BY			**Please choose only ONE**		
	Not at all	A little bit	Moderately	Quite a bit	Extremely
17. Trembling	0	1	2	3	4
18. Feeling that most people cannot be trusted	0	1	2	3	4
19. Poor appetite	0	1	2	3	4
20. Crying easily	0	1	2	3	4
21. Feeling shy or uneasy with the opposite sex	0	1	2	3	4
22. Feeling of being trapped or caught	0	1	2	3	4
23. Suddenly scared for no reason	0	1	2	3	4
24. Temper outbursts that you could not control	0	1	2	3	4
25. Feeling afraid to go out of your house alone	0	1	2	3	4
26. Blaming yourself for things	0	1	2	3	4
27. Pains in lower back	0	1	2	3	4
28. Feeling blocked in getting things done	0	1	2	3	4
29. Feeling lonely	0	1	2	3	4
30. Feeling blue	0	1	2	3	4
31. Worrying too much about things	0	1	2	3	4
32. Feeling no interest in things	0	1	2	3	4
33. Feeling fearful	0	1	2	3	4
34. Your feelings being easily hurt	0	1	2	3	4
35. Other people being aware of your private thoughts	0	1	2	3	4
36. Feeling others do not understand you or are unsympathetic	0	1	2	3	4

For the past week, HOW MUCH WERE YOU BOTHERED BY:	**Please choose only ONE**				
	Not at all	A little bit	Moder-ately	Quite a bit	Extreme-ly
37. Feeling that people are unfriendly or dislike you	0	1	2	3	4
38. Having to do things very slowly to insure correctness	0	1	2	3	4
39. Heart pounding or racing	0	1	2	3	4
40. Nausea or upset stomach	0	1	2	3	4
41. Feeling inferior to others	0	1	2	3	4
42. Soreness of your muscles	0	1	2	3	4
43. Feeling that you are watched or talked about by others	0	1	2	3	4
44. Trouble falling asleep	0	1	2	3	4
45. Having to check and double-check what you do	0	1	2	3	4
46. Difficulty making decisions	0	1	2	3	4
47. Feeling afraid to travel on buses, subways, or trains	0	1	2	3	4
48. Trouble getting your breath	0	1	2	3	4
49. Hot or cold spells	0	1	2	3	4
50. Having to avoid certain things, places, or activities because they frighten you	0	1	2	3	4
51. Your mind going blank	0	1	2	3	4
52. Numbness or tingling in parts of your body	0	1	2	3	4
53. A lump in your throat	0	1	2	3	4
54. Feeling hopeless about the future	0	1	2	3	4
55. Trouble concentrating	0	1	2	3	4
56. Feeling weak in parts of your body	0	1	2	3	4

For the past week,
HOW MUCH WERE YOU BOTHERED BY:

Please choose only ONE

	Not at all	A little bit	Moder-ately	Quite a bit	Extreme-ly
57. Feeling tense or keyed up	0	1	2	3	4
58. Heavy feelings in your arms or legs	0	1	2	3	4
59. Thoughts of death or dying	0	1	2	3	4
60. Overeating	0	1	2	3	4
61. Feeling uneasy when people are watching or talking about you	0	1	2	3	4
62. Having thoughts that are not your own.	0	1	2	3	4
63. Having urges to beat, injure, or harm someone	0	1	2	3	4
64. Awakening in the early morning	0	1	2	3	4
65. Having to repeat the same actions such as touching, counting, washing	0	1	2	3	4
66. Sleep that is restless or disturbed	0	1	2	3	4
67. Having urges to break or smash things	0	1	2	3	4
68. Having ideas or beliefs that others do not share	0	1	2	3	4
69. Feeling very self-conscious with others	0	1	2	3	4
70. Feeling uneasy in crowds, such as shopping or at a movie	0	1	2	3	4
71. Feeling everything is an effort	0	1	2	3	4
72. Spells of terror or panic	0	1	2	3	4
73. Feeling uncomfortable about eating or drinking in public	0	1	2	3	4

For the past week, HOW MUCH WERE YOU BOTHERED BY:	Please choose only ONE				
	Not at all	A little bit	Moderately	Quite a bit	Extremely
74. Getting into frequent arguments	0	1	2	3	4
75. Feeling nervous when you are left alone	0	1	2	3	4
76. Others not giving you proper credit for your achievements	0	1	2	3	4
77. Feeling lonely even when you are with people	0	1	2	3	4
78. Feeling so restless you couldn't sit still	0	1	2	3	4
79. Feelings of worthlessness	0	1	2	3	4
80. Feeling that familiar things are strange or unreal	0	1	2	3	4
81. Shouting or throwing things	0	1	2	3	4
82. Feeling afraid you will faint in public	0	1	2	3	4
83. Feeling that people will take advantage of you if you let them	0	1	2	3	4
84. Having thoughts about sex that bother you a lot	0	1	2	3	4
85. The idea that you should be punished for your sins	0	1	2	3	4
86. Feeling pushed to get things done	0	1	2	3	4
87. The idea that something serious is wrong with your body	0	1	2	3	4
88. Never feeling close to another person	0	1	2	3	4
89. Feelings of guilt	0	1	2	3	4
90. The idea that something is wrong with your mind	0	1	2	3	4

This portion of the questionnaire contains groups of statements. Please read each group of statements carefully. Then pick out the one statement in each group which best describes the way you have been feeling the **PAST WEEK, INCLUDING TODAY.** Circle the number beside the statement you picked. If several statements in the group seem to apply equally well, circle each one. **Be sure to read all the statements in each group before making your choice.**

1. 0 I do not feel sad.
    1 I feel sad.
    2 I am sad all the time and I can't snap out of it.
    3 I am so sad or unhappy that I can't stand it.

2. 0 I am not particularly discouraged about the future.
    1 I feel discouraged about the future.
    2 I feel I have nothing to look forward to.
    3 I feel that the future is hopeless and that things cannot improve.

3. 0 I do not feel like a failure.
    1 I feel I have failed more than the average person.
    2 As I look back on my life, all I see is a lot of failures.
    3 I feel I am a complete failure as a person.

4. 0 I get as much satisfaction out of things as I used to.
    1 I don't enjoy things the way I used to.
    2 I don't get real satisfaction out of anything anymore.
    3 I am dissatisfied or bored with everything.

5. 0 I don't feel particularly guilty.
    1 I feel guilty a good part of the time.
    2 I feel quite guilty most of the time.
    3 I feel guilty all of the time.

6. 0 I don't feel I am being punished.
    1 I feel I may be punished.
    2 I expect to be punished.
    3 I feel I am being punished.

7. 0 I don't feel disappointed in myself.
    1 I am disappointed in myself.
    2 I am disgusted with myself.
    3 I hate myself.

8. 0 I don't feel I am any worse than anybody else.
   1 I am critical of myself for my weaknesses or mistakes.
   2 I blame myself all the time for my faults.
   3 I blame myself for everything bad that happens.

9. 0 I don't have any thoughts of killing myself.
   1 I have thoughts of killing myself, but I would not carry them out.
   2 I would like to kill myself.
   3 I would kill myself if I had the chance.

10. 0 I don't cry any more than usual.
   1 I cry more now than I used to.
   2 I cry all the time now.
   3 I used to be able to cry, but now I can't cry even though I want to.

11. 0 I am no more irritated now than I ever am.
   1 I get annoyed or irritated more easily than I used to.
   2 I feel irritated all the time now.
   3 I don't get irritated at all by the things that used to irritate me.

12. 0 I have not lost interest in other people.
   1 I am less interested in other people than I used to be.
   2 I have lost most of my interest in other people.
   3 I have lost all of my interest in other people.

13. 0 I make decisions about as well as I ever could.
   1 I put off making decisions more than I used to.
   2 I have greater difficulty in making decisions than before.
   3 I can't make decisions at all anymore.

14. 0 I don't feel I look any worse than I used to.
   1 I am worried that I am looking old or unattractive.
   2 I feel that there are permanent changes in my appearance that make me look unattractive.
   3 I believe that I look ugly.

15. 0 I can work about as well as before.
   1 It takes an extra effort to get started at doing something.
   2 I have to push myself very hard to do anything.
   3 I can't do any work at all.

16. 0 I can sleep as well as usual.
    1 I don't sleep as well as I used to.
    2 I wake up 1 - 2 hours earlier than usual and find it hard to get back to sleep.
    3 I wake up several hours earlier than I used to and cannot get back to sleep.

17. 0 I don't get more tired than usual.
    1 I get tired more easily than I used to.
    2 I get tired from doing almost anything.
    3 I am too tired to do anything.

18. 0 My appetite is no worse than usual.
    1 My appetite is not as good as it used to be.
    2 My appetite is much worse now.
    3 I have no appetite at all anymore.

19. 0 I haven't lost much weight, if any lately.
    1 I have lost more than 5 pounds.
    2 I have lost more than 10 pounds.
    3 I have lost more than 15 pounds.

    I am purposely trying to lose weight by eating less. Yes ___ No___

20. 0 I am no more worried about my health than usual.
    1 I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
    2 I am very worried about physical problems and it's hard to think of much else.
    3 I am so worried about my physical problems, that I cannot think about anything else.

21. 0 I have not noticed any recent change in my interest in sex.
    1 I am less interested in sex than I used to be.
    2 I am much less interested in sex now.
    3 I have lost interest in sex completely.

DATE:_____
ID:________

SIX MONTH ASSESSMENT

RISK ASSESSMENT PROJECT

MODIFIED FROM THE NATIONAL INSTITUTE ON DRUG ABUSE AFA

version 2-1/90

1	2	3	4	5	6
Less than 1x/week	1x/week	2 - 6x/ week	1x/day	2-3x/day	4(+)/day

	Non Injected		Freq. Past 6 Mnth	Injected Drug use		Freq Past 6 Mnt
	N	Y		N	Y	
A. Alcohol	0	1		x	x	x
B. Glue/Paint Thinner/Toluene	0	1		x	x	x
C. Marijuana/hashish	0	1		x	x	x
D. Crack/Freebase Cocaine	0	1		x	x	x
E. Cocaine by itself	0	1		0	1	
F. Amphetamine/speed by itself	0	1		0	1	
G. Heroin by itself	0	1		0	1	
H. Heroin & Cocaine mixed together	0	1		0	1	
I. Non Perscription Methadone	0	1		0	1	
J. Other Opiates/Narcotics	0	1		0	1	
K. Barbiturates	0	1		0	1	
L. Tranquilizers	0	1		0	1	
M. PCP	0	1		0	1	
N. Hallucinogens/Psychedelics/MDA	0	1		0	1	
O. Nitrites and Poppers	0	1		0	1	
P. Benzodiazapines	0	1		0	1	
Q. Other Drugs	0	1		0	1	
R. Drugs in Combination:	0	1		0	1	

Section A: Drug Use--*If no injecting in the past six months skip to 6Q13.*

6Q1. How often are you shooting up now?

0	1	2	3	4	5	6
not at all	Less than 1x/week	1x/week	2 - 6x/ week	1x/day	2-3x/day	4(+)/day

6Q2. How long has this been your pattern of use?_____(mths)

6Q3. When was the last time you used a needle after someone else?_____(weeks)

a. Did you clean it first ? ☐ Yes ☐ No How?_____________ Code___

1- Bleach
2- Alcohol
3- Water Only
4- Other

6Q4. Thinking back over the past 6 months, please tell where you have shot drugs most of the time.....Have you shot drugs any other places? (Inteviewer:*Only one most may be circled!*)

		Most	Some	Never
A.	At your own place?	1	2	3
B.	At a friend's place?	1	2	3
C	At a party or social gathering?	1	2	3
D.	At a dealer's house or apartment?	1	2	3
E	At a shooting gallery	1	2	3
F.	In an abandoned building?	1	2	3
G	On the street, in a park, in an alley, or on rooftops?	1	2	3
H.	Some other place (Specify:_____________)?	1	2	3

6Q5. Thinking back about all the times you shot up over the past 6 months, who are the people that you have shot up with?
(**Interviewer**:*Only one most may be circled!*)

	Yes	No	Most	Some	Never
A. Only your spouse or sexual partner:	☐	☐	1	2	3
B. Only your running partner	☐	☐	1	2	3
C Friends/other people you know	☐	☐	1	2	3
D. Strangers	☐	☐	1	2	3
E Shot up alone	☐	☐	1	2	3

6Q5a. Now I'd like to ask you about sharing needles. Thinking back about all the times you shot up over the past 6 months, who are the people that you have shared a needle with?
(**Interviewer**:*Only one most may be circled!*)

		Yes	No	Most	Some	Never
A.	Only your spouse or sexual partner: (shared needles)	☐	☐	1	2	3
B.	Only your running partner (shared needles)	☐	☐	1	2	3
C	Friends or other people you know (shared needles)	☐	☐	1	2	3
D.	Strangers (shared needles)	☐	☐	1	2	3

6Q6. In the past 6 months, have you....

	Yes	No	Most	Some	Never
A. Rented needles or syringes you think had been used?	☐	☐	1	2	3
B. Had someone lend or give you needles or syringes that had been used?	☐	☐	1	2	3
C. Shared a cooker or cotton with someone else?	☐	☐	1	2	3
D. Shared a syringe or needle with someone else?	☐	☐	1	2	3
E. Shared rinse water with someone else?	☐	☐	1	2	3
F. Gotten a needle or syringe in a sterile wrapper?	☐	☐	1	2	3
G. Gotten a needle or syringe in a sterile wrapper, used it once and never used it again?	☐	☐	1	2	3
H. Gotten needles or syringes legally?	☐	☐	1	2	3

6Q7. About how many times do you use a needle before you get rid of it?___

6Q8. In the past six months, how did you get rid of them?
(Interviewer:*Only one most may be circled!*)

		Most	Some	Never
A.	Given or lent them to a running partner?	1	2	3
B.	Given or lent them to a sex partner?	1	2	3
C	Given or lent them to friends or others?	1	2	3
D	Thrown them away?	1	2	3
E	Sold them without cleaning	1	2	3
F.	Cleaned them and then sold or given them away?	1	2	3
H	Cleaned them and reused them yourself?	1	2	3
I.	Other (Specify:____________).	1	2	3

6Q9. In the past 6 months, have you bought a needle that could have been used before?

☐ Yes How Many?______
☐ No

6Q10. In the last 6 months, how often have you cleaned your needles (works, rigs) before you shot drugs?

All	Most	1/2	Some	Never
1	2	3	4	5

6Q11. When you have cleaned your needles (works, rigs) in the last 6 months, what method did you use?

(DO NOT READ TO CLIENT)

A. ☐ Used bleach or clorox and rinsed with water?
B. ☐ Used alcohol and rinsed with water?
C ☐ Boiled in water?
D. ☐ Rinsed in water only?
E ☐ Used some other method
Specify__________________________)

Treatment and Mobility

6Q13. In the past six months, have you been enrolled in drug treatment programs of the following types?
(If client has trouble categorizing, record names of programs to be coded)

Yes
A. ☐Drug detoxification
B. ☐Residential(e.g., therapeutic community)
C ☐Prison/jail treatment program
D. ☐Methadone maintenance
E. ☐Outpatient drug-free
F. ☐Other (Specify:____________________)

6Q14. How many weeks were you in drug treatment during the past 6 months?
(3 months= 12 weeks) ________

6Q15. Are you NOW enrolled in a drug treatment program:

☐ Yes Name:____________________Code:____
☐ No
1- Giuffre
2- Other

IF NOT IN TREATMENT PROGRAM, SKIP TO 6Q18

6Q16. What type of program are you in now?

A. ☐ Drug detoxification
B. ☐ Residential (e.g., therapeutic community)
C ☐ Prison/jail treatment program
D. ☐ Methadone maintenance
E ☐ Outpatient drug-free
F. ☐ Other (Specify:________________)

6Q17. How long have you been in this program?(time since admission, not just past 6 mos.)
Months ________
Years

6Q18.Have you participated in any self-help programs in the last 6 months?

	Yes	# of Meetings
A.	☐ Alcoholics Anonymous	________
B.	☐ Narcotics Anonymous	________
C	☐ Cocaine Anonymous	________

6Q19. Please tell me the cities you have visited/stayed during the past 6 months. Please don't include places where you ONLY spent time in prison or some other institution.

☐ No travel

	City/State	6Q19a. Had Sex? 8=refused 9=N/A		6Q19b. Shot Up? 8=refused 9=N/A		
		Yes	No	Yes	No	Code
A.						
B.						
C						
D.						
E						
F.						
G						
H						

1- New York City
2- North Jersey (e.g.Newark,not Trenton)
3- Puerto Rico
4- Baltimore-Wash.D.C. area
5- South Jersey e.g. Atl. City, Camden
6- Phila. & suburbs
7- Other

6Q20. How many weeks have you been in jail or prison during the past six months? _____

6Q21. Of the times you were in jail or prison in the last 6 months, how many involved a stay of 1 week or longer? _____

6Q22. Where have you spent time in prison or some other type of institution during the past six months:

Code

______________________________ ____

______________________________ ____

1- New York City
2- North Jersey
(e.g.Newark,not Trenton)
3- Puerto Rico
4- Baltimore-Wash.D.C. area
5- South Jersey e.g. Atl. City, Camden
6- Phila. & suburbs
7- Other

6Q23. Are you currently...

No	Yes	
☐	☐	On Probation
☐	☐	On Parole
☐	☐	Facing criminal charges

Sexual Activity

6Q24. Have you had sex with anyone in the last 6 months?

☐ YES
☐ NO (skip to Q 48)

6Q25. How many people have you had sex with in the past 6 months?

NUMBER ____

FOR THOSE WITH ONLY ONE PARTNER:

6Q26. Is your sex partner..

☐ MALE
☐ FEMALE

6Q27. Has (he,she) used drugs intravenously in the past six months?

☐ YES
☐ NO

6Q28. For the past six months about how often have you had sex?
- ☐ more than 1x per day(>180)
- ☐ about 1 time a day(115-180)
- ☐ about every other day (76-114)
- ☐ a few times each week (31-75)
- ☐ about 1 time each week (19-30)
- ☐ a few times each month (6-18)
- ☐ about once each month (<=6)

6Q29. For the past six months, have you had anal intercourse? If yes...
- ☐ more than 1x per day(>180)
- ☐ about 1 time a day(115-180)
- ☐ about every other day (76-114)
- ☐ a few times each week (31-75)
- ☐ about 1 time each week (19-30)
- ☐ a few times each month (6-18)
- ☐ about once each month (<=6)
- ☐ Never

6Q30. During the past six months, how often did you or your sexual partner use birth control?

All	Most	1/2	Some	Never
1	2	3	4	5

what method?____________________________Code:____

1- Condoms 2- Pill 3- IUD 4- Diaphragm/Cream
5- Vasectomy 6- Tubal Ligation(Tubes Tied) 7- Infertile 8-Other

6Q31. If you don't (always) use birth control, why not?

____Code:________

____Code:________

1- Can't get pregnant 2- Wants Pregnancy 3- Don't Like 4- Supplies Unavailable
5- Don't Believe in birth control 6- Steady Relationship(s) 7- Other

6Q32. When you had sex in the past six months, how often did you (or your partner) use a condom?

All	Most	1/2	Some	Never
1	2	3	4	5

6Q33. Why didn't you always use a condom?

____Code:________

____Code:________

1- Can't get pregnant 2- Wants Pregnancy 3- Don't Like 4- Supplies Unavailable
5- Don't Believe in birth control 6- Steady Relationship(s) 7- Other

FOR THOSE WITH MORE THAN ONE PARTNER

6Q34. How many of these partners were female? ________

6Q35. How many of these partners were male? ________

6Q36. How many of these people ever shot drugs intravenously?

	Ever	Past 6 Mths.
Females	________]	[__________
Males	________]	[__________

6Q37. For the past six months about how often have you had sex?

☐ more than 1 time per day (>180)
☐ about 1 time a day (115-180)
☐ about every other day (76-114)
☐ a few times each week (31-75)
☐ about 1 time each week (19-30)
☐ a few times each month (6-18)
☐ about once each month (<=6)

6Q38. For the past six months, have you had anal intercourse? IF yes....

☐ more than 1x per day(>180)
☐ about 1 time a day(115-180)
☐ about every other day (76-114)
☐ a few times each week (31-75)
☐ about 1 time each week (19-30)
☐ a few times each month (6-18)
☐ about once each month (<=6)
☐ Never

6Q39. In the past 6 months, have you:...

		Times
(a)	☐ Had sex to get money:	______
(b)	☐ Had sex to get drugs:	______
(c)	☐ Given money to someone for sex:	______
(d)	☐ Given drugs to someone for sex:	______

6Q40. During the past six months, how often did you or your sexual partners use birth control?

All	Most	1/2	Some	Never
1	2	3	4	5

what method?____________________________Code:____

1- Condoms 2- Pill 3- IUD 4- Diaphragm/Cream
5- Vasectomy 6- Tubal Ligation(Tubes Tied) 7- Infertile 8-Other

6Q41. If you don't (always) use birth control, why not?

____Code:____________
____Code:____________

1- Can't get pregnant 2- Wants Pregnancy 3- Don't Like 4- Supplies Unavailable
5- Don't Believe in birth control 6- Steady Relationship(s) 7- Other

6Q42. When you had sex in the past six months, how often did you (or your partners) use a condom?

All	Most	1/2	Some	Never
1	2	3	4	5

6Q43. Why didn't you always use a condom?

____Code:____________
____Code:____________
____Code:____________

1- Can't get pregnant 2- Wants Pregnancy 3- Don't Like 4- Supplies Unavailable
5- Don't Believe in birth control 6- Steady Relationship(s) 7- Other

6Q44. How much of the time do you shoot up before having sex?

All	Most	1/2	Some	Never
1	2	3	4	5

6Q45. How much of the time do you drink (beer, wine, or liquor) before having sex?

All	Most	1/2	Some	Never
1	2	3	4	5

6Q46. How much of the time do you get high on cocaine before having sex?

All	Most	1/2	Some	Never
1	2	3	4	5

6Q47. How much of the time do you get high on other drugs (marijuana, valium, zanax, etc.), before having sex?

All	Most	1/2	Some	Never
1	2	3	4	5

Health

6Q48. How would you describe your health for the past 6 months?

☐ Excellent
☐ Good
☐ Fair
☐ Poor

6Q49. Have you had sores in the genital area in the past six months?
☐ Yes
☐ No

Ask of FEMALES ONLY.

6Q50. Did you become pregnant during the past six months?
☐ Yes ☐ No

6Q51. Are you currently pregnant?
☐ Yes
☐ No

6Q52. In the past 6 months, have you been told by a doctor or nurse that you had.........

		LAST 6 MONTHS? (0=no; 1=yes; 7=DK/Unsure; 8=refused;
A.	Pneumonia	____
B.	Hepatitis	____
C	Tuberculosis	____
D.	Endocarditis	____
E	Genital Herpes	____
F.	Gonorrhea (Clap)	____
G	Syphilis	____
H.	Chlamydia (NGU, Non-Gonococcal Urethritis)?	____
I.	AIDS-Related Complex or ARC?	____
J.	AIDS?	____

6Q53. Do you have health Insurance
☐ MA
☐ BC/BS
☐ HMO
☐ None
☐ Other:________________

6Q54. Where do you go for medical care when you get sick?
- ☐ Doctor(private practice)
- ☐ Clinic(City health clinic)
- ☐ Hospital Emergency room:______________________
- ☐ Doctor at programs (methadone, school, work site, etc.)
- ☐ No place
- ☐ Other:______________________

6Q55. Have you donated or sold blood in the past six months?
- ☐ Yes
- ☐ No How many times?______

AIDS and HIV Testing

6Q56. Out of 10 IV drug users how many do you think would be HIV positive? ________*(X 10=_____%)*

6Q57. How likely do you think you are to develop AIDS? Would you say you have...
- ☐ No chance
- ☐ Some chance
- ☐ High chance
- ☐ Sure chance

6Q58. In the last 6 months, ***not including our test,*** have you had a blood test anywhere else for the AIDS virus antibodies?
- ☐ Yes
- ☐ No

6Q58a. **If Yes,** how many times? ____________

6Q58b. Did you get the results?
- ☐ No
- ☐ Yes

6Q58c. What were the results?
- ☐ Positive
- ☐ Negative
- ☐ Never found out
- ☐ refused to answer

AIA 3.0 - SECTION G: AIDS INFORMATION SHEET

INTERVIEWER READ: One important aim of this program is to help people learn more about AIDS. Since we need to find out what people know about AIDS, you can help by answering a few more questions. When we get through, I'll give you the right answers. For now, just say whether you think they are "TRUE, FALSE."

		TRUE	FALSE	DK/UNSURE
1.	If a person is positive on the blood test for the AIDS virus, that means the person has AIDS.	1	0	7
2.	Anyone having sex with only one other person cannot get the AIDS virus.	1	0	7
3.	Using a latex condom is thought to be an effective way to keep from getting the AIDS virus during sex.	1	0	7
4.	A person cannot get the AIDS virus from works/rigs bought on the street in a sealed wrapper.	1	0	7
5.	A person cannot get the AIDS virus by shaking hands or touching someone who has AIDS.	1	0	7
6.	A person can get the AIDS virus from donating blood or plasma.	1	0	7
7.	A woman with the AIDS virus can give her unborn child AIDS.	1	0	7
8.	Cleaning works/rig with just water is enough to kill the AIDS virus.	1	0	7
9.	A person can get the AIDS virus from eating in a restaurant where the cook has AIDS.	1	0	7
10.	Cleaning works/rigs with bleach is thought to be an effective way of killing the AIDS virus.	1	0	7
11.	A person can avoid getting the AIDS virus by just having oral sex.	1	0	7
12.	A person can get the AIDS virus by using public toilets.	1	0	7
13.	A person can get the AIDS virus from having sex with a man who has had sex with other men.	1	0	7
14.	A person can get the AIDS virus from having unprotected sex with someone who has AIDS.	1	0	7
15.	A person can get the AIDS virus from sharing dirty works/rigs with someone who has AIDS.	1	0	7

RAP (PHASE 2) CONTACT SHEET

AME: ______________________ VETERAN: Y__ N__

ROBATION: Y__ N__ PAROLE: Y__ N__ FACING CHARGES: Y__ N__

ROB./PAR. OFFICER: ______________ COUNSELOR: ______________

IVING IN A SHELTER: Y__ N__ NO STABLE ARRANGEMENT: __

DDRESS: ______________________________ PHONE: ____________

____

ILL YOU BE AT THIS ADDRESS IN SIX MONTHS: Y__ N__
F NO, PLACE FUTURE ADDRESS ON BACK.

OTHER CONTACTS

AME: ______________________ RELATIONSHIP: ____________

DDRESS: ______________________________ PHONE: ____________

____

AME: ______________________ RELATIONSHIP: ____________

DDRESS: ______________________________ PHONE: ____________

____

AME: ______________________ RELATIONSHIP: ____________

DDRESS: ______________________________ PHONE: ____________

____

AIA 8.0 - SECTION I: INTERVIEWER COMMENTS AND OBSERVATIONS

I. INTERVIEWER COMMENTS AND OBSERVATIONS

1. Is this questionnaire/interview unreliable? _____YES _____NO

IF "YES", CIRCLE THOSE SECTIONS YOU BELIEVE ARE UNRELIABLE.

SECTIONS: A B C D E F G ALL

Explain:____

____

____

2. Interviewer impression of respondent (CHECK AS MANY AS APPLY);

___ Honest
___ Dishonest
___ High
___ Nodding
___ Relaxed
___ Tense
___ Attentive
___ Distracted
___ Interested
___ Bored
___ Good Rapport (Open)
___ Resistant

3. Mood of interview

Comments: ____

____

____

4. Locator Information

A. Were you able to collect follow-up locator information?(Circle one)

0=No; 1=Yes; 8=Refused

B. Interviewer assessment of quality of locator information.(Circle one)

1=Complete 3=Marginal

2=Sufficient 4=Inadequate

5. Interviewer characteristics: CIRCLE ONE IN EACH CATEGORY

A. 1=Indigenous; 2=Professionally trained

B. 1=Outreach worker; 2=interviewer only; 3=Program staff

C. Interviewer Sex 1=Male 2=Female

D. Interviewer Race/Ethnicity: ________________________________
Self fill-in

E. Interviewer Name: ________________________________

INSTRUCTIONS

1. Leave No Blanks — Where appropriate code items: X = question not answered
   N = question not applicable
   Use only one character per item.
2. Item numbers circled are to be asked at follow-up. Items with an asterisk are cumulative and should be rephrased at follow-up (see Manual).
3. Space is provided after sections for additional pertinent information.

ADDICTION SEVERITY INDEX

SEVERITY RATINGS

The severity ratings are interviewer estimates of the patient's need for additional treatment in each area. The scales range from 0 (no treatment necessary) to 9 (treatment needed to intervene in life-threatening situation). Each rating is based upon the patient's history of problem symptoms, present condition and subjective assessment of his treatment needs in a given area. For a detailed description of severity ratings' derivation procedures and conventions, see manual.

Third Edition

SUMMARY OF PATIENTS RATING SCALE

0 - Not at all
1 - Slightly
2 - Moderately
3 - Considerably
4 - Extremely

I.D. NUMBER ☐☐☐☐

LAST 4 DIGITS OF SSN ☐☐☐☐

DATE OF ADMISSION ☐☐☐☐☐☐

DATE OF INTERVIEW ☐☐☐☐☐☐

TIME BEGUN ☐☐ : ☐☐

TIME ENDED ☐☐ : ☐☐

CLASS: ☐
1 - Baseline 3 - 12mo
2 - 6 mo 4 - 15 mo

CONTACT CODE: ☐
1 - In Person
2 - Phone
3 - Mail

GENDER: ☐
1 - Male
2 - Female

TREATMENT EPISODE NUMBER ☐☐

INTERVIEWER CODE NUMBER ☐☐

SPECIAL: ☐
1 - Patient terminated
2 - Patient refused
3 - Patient unable to respond

GENERAL INFORMATION

NAME ______________________

CURRENT ADDRESS ______________________
____
____

GEOGRAPHIC CODE ☐☐

1. How long have you lived at this address? ☐☐ yrs. ☐☐ mos.
2. Is this residence owned by you or your family? ☐
   0 - No 1 - Yes
3. DATE OF BIRTH ☐☐☐☐☐☐
4. RACE ☐
   1 - White (Not of Hispanic Origin)
   2 - Black (Not of Hispanic Origin)
   3 - American Indian
   4 - Alaskan Native
   5 - Asian or Pacific Islander
   6 - Hispanic - Mexican
   7 - Hispanic - Puerto Rican
   8 - Hispanic - Cuban
   9 - Other Hispanic
5. RELIGIOUS PREFERENCE ☐
   1 - Protestant 4 - Islamic
   2 - Catholic 5 - Other
   3 - Jewish 6 - None

⑥ Have you been in a controlled environment in the past 30 days? ☐
1 - No
2 - Jail
3 - Alcohol or Drug Treatment
4 - Medical Treatment
5 - Psychiatric Treatment
6 - Other ______________

⑦ How many days? ☐☐

TEST RESULTS

Shipley
C.Q. ☐☐☐
I.Q. ☐☐☐

Beck
Total Score ☐☐

CARD 1

SEVERITY PROFILE

9							
8							
7							
6							
5							
4							
3							
2							
1							
0							
PROBLEMS	MEDICAL	EMP/SUP	ALCOHOL	DRUG	LEGAL	FAM/SOC	PSYCH

____
Interviewer Signature

Patient I.D. Card Imprint

I.D. 1 ☐☐☐☐

MEDICAL STATUS

* ① How many times in your life have you been hospitalized for medical problems? 5 ☐☐
(Include o.d.'s, d.t.'s, exclude detox.)

2. How long ago was your last hospitalization for a physical problem? ☐☐ YRS. ☐☐ MOS.

3. Do you have any chronic medical problems which continue to interfere with your life? ☐
0 - No 1 - Yes

④ Are you taking any prescribed medication on a regular basis for a physical problem? ☐
0 - No 1 - Yes

⑤ Do you receive a pension for a physical disability? *(Exclude psychiatric disability.)* ☐
0 - No
1 - Yes ______________ _____
Specify

⑥ How many days have you experienced medical problems in the past 30? ☐☐

FOR QUESTIONS 7 & 8 PLEASE ASK PATIENT TO USE THE PATIENT'S RATING SCALE.

⑦ How troubled or bothered have you been by these medical problems in the past 30 days? ☐

⑧ How important to you *now* is treatment for these medical problems? ☐

INTERVIEWER SEVERITY RATING

⑨ How would you rate the patient's need for medical treatment? ☐

CONFIDENCE RATINGS

Is the above information significantly distorted by:

⑩ Patient's misrepresentation? ☐
0 - No 1 - Yes

⑪ Patient's inability to understand? 20 ☐
0 - No 1 - Yes

COMMENTS

EMPLOYMENT/SUPPORT STATUS

* ① Education completed *(GED = 12 years)* ☐☐ YRS. ☐☐ MOS.

* ② Training or technical education completed ☐☐ MOS.

3. Do you have a profession, trade or skill? ☐
0 - No
1 - Yes ____________________
Specify

④ Do you have a valid driver's license? ☐
0 - No 1 - Yes

⑤ Do you have an automobile available for your use? *(Answer No if no valid driver's license.)* ☐
0 - No 1 — Yes

6. How long was your longest full-time job? ☐☐ YRS. ☐☐ MOS.

* ⑦ Usual (or last) occupation. ☐
____
(Specify in detail)

⑧ Does someone contribute to your support in any way? ☐
0 - No 1 - Yes

⑨ (ONLY IF ITEM 8 IS YES)
Does this constitute the majority of your support? ☐
0 - No 1 - Yes

10. Usual employment pattern, past 3 years. ☐
1 - full time (40 hrs/wk)
2 - part time (reg. hrs)
3 - part time (irreg., daywork)
4 - student
5 - service
6 - retired/disability
7 - unemployed
8 - in controlled environment

⑪ How many days were you paid for working in the past 30? *(Include "under the table" work.)* ☐☐

How much money did you receive from the following sources in the past 30 days?

⑫ Employment *(net income)* ☐☐☐☐

⑬ Unemployment compensation ☐☐☐☐

⑭ DPA ☐☐☐☐

⑮ Pension, benefits or social security ☐☐☐☐

⑯ Mate, family or friends *(Money for personal expenses).* ☐☐☐☐

⑰ Illegal ☐☐☐☐

⑱ How many people depend on you for the majority of their food, shelter, etc.? ☐

⑲ How many days have you experienced employment problems in the past 30? ☐☐

FOR QUESTIONS 20 & 21 PLEASE ASK PATIENT TO USE THE PATIENT'S RATING SCALE

⑳ How troubled or bothered have you been by these employment problems in the past 30 days? ☐

㉑ How important to you *now* is counseling for these employment problems? ☐

INTERVIEWER SEVERITY RATING

㉒ How would you rate the patient's need for employment counseling? ☐

CONFIDENCE RATINGS

Is the above information significantly distorted by:

㉓ Patient's misrepresentation? ☐
0 - No 1 - Yes

㉔ Patient's inability to understand? 71 ☐
0 - No 1 - Yes

CARD 2 80

COMMENTS

I.D. 1 ☐☐☐☐

CODE#

	PAST 30 DAYS	LIFETIME USE YRS.	MOS.
(01)- Alcohol - Any use at all	☐☐	☐☐	☐☐
(02)- Alcohol - To intoxication	☐☐	☐☐	☐☐
(03)- Heroin	☐☐	☐☐	☐☐
(04)- Methadone	☐☐	☐☐	☐☐
(05)- Other opiates/ analgesics	☐☐	☐☐	☐☐
(06)- Barbiturates	☐☐	☐☐	☐☐
(07)- Other sed/ hyp/tranq.	☐☐	☐☐	☐☐
(08)- Cocaine	☐☐	☐☐	☐☐
(09)- Amphetamines	☐☐	☐☐	☐☐
⑩- Cannabis	☐☐	☐☐	☐☐
⑪- Hallucinogens	☐☐	☐☐	☐☐
⑫- Inhalants	☐☐	☐☐	☐☐

CARD 3

Note: See manual for representative examples for each drug class

I.D. 1 ☐☐☐☐

⑬ More than one substance per day *(Incl. alcohol).* ☐☐ DAYS ☐☐ YRS. ☐☐ MOS.

DRUG/ALCOHOL USE

⑭ Which substance is the major problem? *Please code as above or 00-No problem;* 15-Alcohol & Drug (Dual addiction); 16-Polydrug; *when not clear, ask patient.* ☐☐

15. How long was your last period of voluntary abstinence from this major substance? *(00 - never abstinent).* ☐☐ MOS.

16. How many months ago did this abstinence end? *(00 - still abstinent).* ☐☐

*⑰ How many times have you:

Had alcohol d.t.'s ☐☐

Overdosed on drugs ☐☐

*⑱ How many times in your life have you been treated for:

Alcohol Abuse ☐☐

Drug Abuse ☐☐

*⑲ How many of these were detox only?

Alcohol ☐☐

Drug ☐☐

⑳ How much would you say you spent during the past 30 days on:

Alcohol ☐☐☐☐

Drugs ☐☐☐☐

㉑ How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days *(Include NA, AA).* ☐☐

㉒ How many days in the past 30 have you experienced:

Alcohol Problems ☐☐

Drug Problems ☐☐

FOR QUESTIONS 23 & 24 PLEASE ASK PATIENT TO USE THE PATIENT'S RATING SCALE

㉓ How troubled or bothered have you been in the past 30 days by these:

Alcohol Problems ☐

Drug Problems ☐

㉔ How important to you *now* is treatment for these:

Alcohol Problems ☐

Drug Problems ☐

INTERVIEWER SEVERITY RATING

㉕ How would you rate the patient's need for treatment for:

Alcohol Abuse ☐

Drug Abuse ☐

CONFIDENCE RATINGS

Is the above information significantly distorted by:

㉖ Patient's misrepresentation? ☐

0 — No 1 — Yes

㉗ Patient's inability to understand? ☐

0 — No 1 — Yes

CARD 4

COMMENTS

I.D. 1 ☐☐☐☐

1. Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)? ☐
   0 — No 1 — Yes

② Are you on probation or parole? ☐
   0 — No 1 — Yes

How many times in your life have you been arrested and charged with the following criminal offenses:

CODE #

*③	shoplifting/vandalism	☐☐
*④	parole/probation violations	☐☐
*⑤	drug charges	☐☐
*⑥	forgery	☐☐
*⑦	weapons offense	☐☐
*⑧	burglary, larceny, B & E	☐☐
*⑨	robbery	☐☐
*⑩	assault	☐☐
*⑪	arson	☐☐
*⑫	rape	☐☐
*⑬	homicide, manslaughter	☐☐
*⑭	other	☐☐

LEGAL STATUS

*⑮ How many of these charges resulted in convictions? ☐☐

How many times in your life have you been charged with the following:

*⑯ Disorderly conduct, vagrancy, public intoxication ☐☐

*⑰ Driving while intoxicated ☐☐

*⑱ Major driving violations (reckless driving, speeding, no license, etc.). ☐☐

*⑲ How many months were you incarcerated in your life? ☐☐ MOS

20. How long was your last incarceration? ☐☐ MOS

21. What was it for? *(Use code 3-14, 16-18. If multiple charges, code most severe)* ☐☐

㉒ Are you presently awaiting charges, trial or sentence? ☐
   0 — No 1 — Yes

㉓ What for? *(If multiple charges, use most severe).* ☐☐

㉔ How many days in the past 30 were you detained or incarcerated? ☐☐

㉕ How many days in the past 30 have you engaged in illegal activities for profit? ☐☐

FOR QUESTIONS 26 & 27 PLEASE ASK PATIENT TO USE THE PATIENT'S RATING SCALE

㉖ How serious do you feel your present legal problems are? *(Exclude civil problems)* ☐

㉗ How important to you *now* is counseling or referral for these legal problems? ☐

INTERVIEWER SEVERITY RATING

㉘ How would you rate the patient's need for legal services or counseling? ☐

CONFIDENCE RATINGS

Is the above information significantly distorted by:

㉙ Patient's misrepresentation? ☐
   0 — No 1 — Yes

㉚ Patient's inability to understand? 58 ☐
   0 — No 1 — Yes

CARD 5 80

COMMENTS

I.D. 1 ☐☐☐☐

① Marital Status ☐
1 - Married
2 - Remarried
3 - Widowed
4 - Seperated
5 - Divorced
6 - Never Married

2. How long have you been in this marital status? ☐☐ YRS. ☐☐ MOS.
(If never married, since age 18).

③ Are you satisfied with this situation? ☐
0 - No
1 - Indifferent
2 - Yes

*④ Usual living arrangements (past 3 yr.) ☐
1 - With sexual partner and children
2 - With sexual partner alone
3 - With parents
4 - With family
5 - With friends
6 - Alone
7 - Controlled environment
8 - No stable arrangements

5. How long have you lived in these arrangements. ☐☐ YRS. ☐☐ MOS.
(If with parents or family, since age 18).

⑥ Are you satisfied with these living arrangements? ☐
0 - No
1 - Indifferent
2 - Yes

FAMILY/SOCIAL RELATIONSHIPS

⑦ With whom do you spend most of your free time: ☐
1 - Family
2 - Friends
3 - Alone

⑧ Are you satisfied with spending your free time this way? ☐
0 - No
1 - Indifferent
2 - Yes

⑨ How many close friends do you have? ☐☐

⑩ How many days in the past 30 have you had serious conflicts:
Ⓐ with your family? ☐☐
Ⓑ with other people? (excluding family). ☐☐

Have you had significant periods in which you have experienced serious problems with:
0 - No 1 - Yes

	PAST 30 DAYS	IN YOUR LIFE
⑪ Mother	☐	☐
⑫ Father	☐	☐
⑬ Brother/Sisters	☐	☐
⑭ Sexual partner/spouse	☐	☐
⑮ Children	☐	☐
⑯ Other significant family ________	☐	☐
⑰ Close friends	☐	☐
⑱ Neighbors	☐	☐
⑲ Co-workers	☐	☐

FOR QUESTIONS 20-23 PLEASE ASK PATIENT TO USE THE PATIENT'S RATING SCALE

How troubled or bothered have you been in the past 30 days by these:
⑳ Family problems? ☐
㉑ Social problems? ☐

How important to you now is treatment or counseling for these:
㉒ Family problems? ☐
㉓ Social problems? ☐

INTERVIEWER SEVERITY RATING

㉔ How would you rate the patient's need for family and/or social counseling? ☐

CONFIDENCE RATINGS

Is the above information significantly distorted by:

㉕ Patient's misrepresentation? ☐
0 - No 1 - Yes

㉖ Patient's inability to understand? ☐
0 - No 1 - Yes

CARD 6

COMMENTS
(Please add extra comments on back of page)

I.D. 1 ☐☐☐☐

*① How many times have you been treated for any psychological or emotional problems?
In a hospital ☐☐
As an Opt. or Priv. patient ☐☐

2. Do you receive a pension for a psychiatric disability? ☐
0 - No 1 - Yes

Have you had a signficant period, (that was not a direct result of drug/alcohol use), in which you have:
0 - No 1 - Yes

	PAST 30 DAYS	IN YOUR LIFE
③ Experienced serious depression	☐	☐
④ Experienced serious anxiety or tension	☐	☐
⑤ Experienced hallucinations	☐	☐
⑥ Experienced trouble understanding, concentrating or remembering	☐	☐
⑦ Experienced trouble controlling violent behavior	☐	☐
⑧ Experienced serious thoughts of suicide	☐	☐
⑨ Attempted suicide	☐	☐
⑩ Have you taken prescribed medication for any psychological/emotional problem	☐	☐

PSYCHOLOGICAL STATUS

⑪ How many days in the past 30 have you experienced these psychological or emotional problems? ☐☐

FOR QUESTIONS 12 & 13 PLEASE ASK PATIENT TO USE THE PATIENT'S RATING SCALE

⑫ How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? ☐

⑬ How important to you now is treatment for these psychological problems? ☐

THE FOLLOWING ITEMS ARE TO BE COMPLETED BY THE INTERVIEWER

At the time of this interview, is patient:
0 - No 1 - Yes

⑭ Obviously depressed/withdrawn ☐

⑮ Obviously hostile ☐

⑯ Obviously anxious/nervous ☐

⑰ Having trouble with reality testing, thought disorders, paranoid thinking ☐

⑱ Having trouble comprehending, concentrating, remembering ☐

⑲ Having suicidal thoughts ☐

INTERVIEWER SEVERITY RATING

⑳ How would you rate the patient's need for psychiatric/psychological treatment? ☐

CONFIDENCE RATINGS

Is the above information significantly distorted by:

㉑ Patient's misrepresentations? ☐
0 - No 1 - Yes

㉒ Patient's inability to understand? ☐
0 - No 1 - Yes

CARD 7

COMMENTS
(Please add extra comments on back of page)

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New Data from the Addiction Severity Index

Reliability and Validity in Three Centers

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CHARLES P. O'BRIEN, M.D., PH.D.[1]

The Addiction Severity Index (ASI) is a clinical/research instrument which has been in wide use during the past 6 years to assess the treatment problems found in alcohol- and drug-abusing patients. In a study of male veterans, a preliminary evaluation of the ASI has indicated reliability and validity. The present report presents an expanded examination of these issues; 181 subjects from three treatment centers were studied. Results of concurrent reliability studies indicate that trained technicians can estimate the severity of patients' treatment problems with an average concordance of .89. Test-retest studies show that the information obtained from the ASI is consistent over a 3-day interval, even with different interviewers. Comparisons of the ASI severity ratings and composite measures with a battery of previously validated tests indicate evidence of concurrent and discriminant validity. The reliability and validity results were consistent across subgroups of patients categorized by age, race, sex, primary drug problem, and treatment center. The authors discuss the strengths and limitations of the instrument based upon 5 years of use. The overall conclusion is that the ASI is a reliable and valid instrument that has a wide range of clinical and research applications, and that it may offer advantages in the examination of important issues such as the prediction of treatment outcome, the comparison of different forms of treatment, and the "matching" of patients to treatments.

The Addiction Severity Index (ASI) was introduced in 1979 as a comprehensive, clinical/research instrument designed to assess the multiple problems seen in alcohol- and drug-dependent persons seeking treatment (16, 17). The instrument was developed to produce information that would be relevant for both clinical and research evaluations. Thus, the interview was designed to be appropriate for use within a variety of alcohol and drug treatment settings, suitable for administration by a trained technician in less than an hour, and suitable for repeat administrations at post-treatment follow-up evaluations (17). Information from ASI interviews has been used by clinical staff for the initial intake evaluation, for treatment planning, and for referral decisions. Since the ASI is computer coded and provides quantitative, time-based assessments of patient status in several areas, researchers have used the ASI to evaluate patient improvements following treatment.

During the past 5 years, our clinical research group has used the ASI extensively to evaluate and compare different forms of alcohol and drug abuse treatments (16–18) and to explore methods of "matching" patients to the most effective treatments available (14, 19, 20). More recently, a number of other investigators have used the ASI in individual treatment evaluations (9, 14), examinations of patient subgroups (21), and in collaborative, multicenter studies of substance abuse treatments.[4,5]

Our initial evaluation of the ASI (16) indicated that it was quite reliable and showed good preliminary evidence of validity. This initial evaluation, other work by independent investigators (13, 21), and the clear need within the field for a reliable, valid, and practical evaluation instrument, has promoted some general acceptance of the ASI (see Reference 8). However, it should be recognized that the majority of work with this instrument has been with male, veteran populations. Thus, many questions remained which required a more complete evaluation of the reliability and validity of the ASI in the general population of substance-abusing patients, particularly in subgroups of women, adolescents of both sexes, and patients

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The authors acknowledge the special help of Mack West, Barbara Herr, and Richard Parente in the collection of these data.

[4] Dorus, W., Collins, V., Ling, W., and Ostrow, D. Lithium in the treatment of alcohol dependence. Veterans Administration Cooperative Study 228, 1982.

[5] Joint Commission on Accreditation of Hospitals. Evaluation report. Philadelphia, August 1983.

from higher socioeconomic strata. To this end, this paper presents the results of our extended evaluation of ASI reliability and validity in a sample of 181 patients admitted to three treatment centers. A discussion of the strengths and limitations of the ASI in both clinical and research use, based upon 6 years of experience, is also presented.

Design of the ASI

The ASI is a structured, 40-minute, clinical research interview designed to assess problem severity in seven areas commonly affected in substance abusers: medical condition, employment, drug use, alcohol use, illegal activity, family relations, and psychiatric condition. In each of the areas, objective questions are asked that measure the number, extent, and duration of problem symptoms in the patient's lifetime and in the past 30 days. The patient also supplies a subjective report of the recent (past 30 days) severity and importance of each problem area. The design and rationale for the ASI have been described elsewhere (15, 16).

Two types of measures result from the collected data in each problem area: severity ratings and composite scores.

Severity Ratings

The final section of each problem area is a 10-point (0 to 9) *interviewer rating* of problem severity. Within the ASI, severity is considered as "need for additional treatment," and is measured by the number, duration, and intensity of problem symptoms. Although the problem severity ratings are ultimately subjective, the ASI is designed to maximize the use of the objective information in formulating these ratings. In practice, the interviewer develops a preliminary rating of problem severity (4-point bracket) upon completion of the objective section. After completion of the subjective section, the interviewer modifies his or her preliminary rating based upon the patient's responses (within a 2-point bracket). Thus, both the rating method and the data upon which the rating is based are standardized, thereby reducing inter-rater variation. An instruction manual detailing the administration procedures is available from the senior author.

Composite Scores

The second type of measure available from the data in each ASI problem area is a mathematically derived composite score. These composite scores are developed from sets of interrelated items within each problem area. These items are standardized and summed to produce a mathematical estimate of patients' status in each of the ASI problem areas. The composite scores are well related to the severity ratings (average correlation = .88) and offer a more empirical evaluation of patient change and treatment effectiveness (see References 17, 19, 20). A manual describing the rationale and construction of these composite scores is available from the senior author.

Methods

Treatment Centers

Three treatment centers participated in this research because of their interest in the instrument and the diversity of their patient populations.

Philadelphia Veterans Administration (VA) Drug Dependence Treatment Unit. This multidisciplinary treatment facility has been in existence for 13 years and offers methadone maintenance, narcotic antagonist, and drug-free outpatient treatment to any veteran who requests drug dependence rehabilitation.

Eagleville Hospital. The Eagleville Hospital was a pioneer in the combined treatment of alcohol and drug abusers. The facility is located in a rural setting, 25 miles from Philadelphia. This treatment center offers inpatient, abstinence-oriented therapeutic community treatment to alcohol- and drug-abusing patients in a combined residential setting.

Carrier Foundation. The Carrier Foundation is part of a large, privately funded psychiatric treatment facility located in a suburban community, 12 miles from Princeton, New Jersey. Separate alcohol and drug abuse treatment facilities are maintained and all treatment is inpatient, abstinence-oriented, therapeutic community.

All three programs offer a number of ancillary support services to substance abuse patients, including: medical care and hospitalization, employment counseling and skills training, family and couples therapy, individual and group psychotherapy, as well as appropriate pharmacotherapy. All three centers are approved by the Joint Commission on Accreditation of Hospitals for the treatment of alcohol and drug abuse.

Subjects

A total of 181 voluntary subjects were recruited at the time of their admission to treatment. Fifty-seven male drug-dependent patients were recruited from the Philadelphia VA. Sixty subjects participated from the Carrier Foundation (15 female and 22 male alcohol dependent; 15 female and eight male drug dependent). Sixty-four patients/subjects participated from the Eagleville Hospital (11 female and 10 male alcohol dependent; 24 female and 19 male drug dependent).

As indicated above, a major reason for selecting the three centers was the difference in their patient populations. For example, Eagleville subjects were younger than Philadelphia VA or Carrier patients (mean ages were 31, 33, 35, respectively). In addition, 88 and 73% of Carrier and Eagleville patients (respectively) were white as compared with 42% of Philadelphia VA patients. Forty-two and 53% of Philadelphia VA and Carrier patients (respectively) had been married, as compared with only 8% of Eagleville patients. Carrier patients had an average monthly income from employment of $1300, 7% received welfare income, and fewer than 10% had been arrested. In contrast, Philadelphia VA subjects averaged $800 per month from employment, 39% received welfare income, and 57% had been arrested. The average monthly employment income for Eagleville patients was less than $600, 44% received welfare income, and 72% had been arrested.

The total sample has been divided into subgroups based upon sex and type of chemical dependence in Table 1, and a range of background characteristics from the ASI is presented for each group. As expected, there were substantial differences among the subgroups on most variables, but particularly in the demographic characteristics of age, race, marital status, living arrangement, and criminal involvement.

Part I. Reliability Studies

Both concurrent and test-retest reliabilities were measured in the present studies. Eight research technicians and treatment counselors were used as judges. Four of these judges had had prior experience with the ASI, and the other four received a 4-day training and supervision course to instruct them in the use of the ASI. Four judges were female and four were male; all were white: three had had primary experience in counseling whereas the other five had no substantial clinical experience with patients. Six judges had a Bachelor's degree and two had a Master of Social Work degree.

Concurrent reliability. Concurrent reliability is the extent of agreement among different judges using the *same information at the same time.* In the concurrent reliability design, 30 subjects (10 from each center) were randomly selected for interview by one of three judges also randomly selected to be the interviewers. Each interview was videotaped and subsequently viewed by the remaining seven judges. The severity ratings on the seven problem areas were compared among the judges and across all patients.

The concurrent reliability coefficients for each ASI scale were calculated for the 30 subjects by using two methods. We first calculated reliability by using the Spearman-Brown formula (25). This method assesses the ratio of variability within the judges' ratings, to the variability across all patients (adjusted for the number of judges). We have reported this method of calculating reliability in our earlier work, (15, 16) and again, the coefficients were very high and quite uniform across all scales ranging from .94 (Family) to .99 (Drug). However, since there were extreme differences among the substance abuse patients on almost every status measure, we considered the possibility that these coefficients were somewhat artificially elevated due to the low interjudge variability relative to the high interpatient variability.

As a test of this possibility, we performed a second

TABLE 1

Background Characteristics of Patients/Subjects by Sex and Substance of Abuse

	Female Alcohol	Male Alcohol	All Alcohol	Female Drug	Male Drug	All Drug	Total
N	26	32	58	39	84	123	181
Age	41	40	41	28	30	30	34
% White	79	72	76	79	59	64	69
% Black	21	28	24	21	41	36	31
Years education	12.5	12.5	12	11	11.5	11.5	11.5
Years alcohol abuse	6	6	6	3	2	2	3
Years opiate abuse	0	0	0	1	4	3	1
Years nonopiate abuse	1	1	1	4	4	4	3
% Working	32	34	34	38	33	34	34
% Receiving welfare	41	32	36	51	40	44	41
% Arrested	4	19	12	5	34	25	16
% Probation/parole	4	16	10	5	29	20	16
% Married/remarried	50	38	44	18	26	26	35
% Divorced/separated	32	37	34	38	24	27	30
% Never married	18	25	22	44	50	47	35
% Live alone	21	19	21	11	18	15	18
% Treated for psychiatric problems	21	9	12	26	12	16	14
% Hospitalized for psychiatric problems	11	4	6	8	8	8	7

reliability calculation by intercorrelating the ratings of the eight judges across all 30 patients on each of the ASI scales. We then averaged these intercorrelations to produce the mean product-moment correlations of the eight judges on each of the seven scales (see Reference 3 for a discussion of this method). These coefficients were lower and less uniform across the scales than the Spearman-Brown coefficients ranging from .74 (Employment) to .91 (Drug). However, they were still indicative of satisfactory reliability. Nonetheless, a potential problem occurs with this method of calculating reliability, at least for these data. There was very little range in the judges' estimates of severity for any single case. That is, the eight judges rated most cases and most problem areas within 1 to 3 points of each other on the 10-point scales and no set of ratings differed by more than 4 points on any scale. This low variability among the judges' ratings would of course have the effect of artificially lowering the intercorrelation coefficients. Paradoxicaly, the correlations would be lowest for those cases where agreement among judges was highest.

Thus, while the Spearman-Brown formula may, due to extreme variability among patients, produce a somewhat artificially high estimate of reliability, the intercorrelation method may, due to the low variability among judges, produce an artificially low estimate of reliability. For this reason, we have taken the position that the two methods represent upper and lower limits of reliability estimates. In subsequent discussions of reliability we will present the mean coefficients produced by averaging the Spearman-Brown and the intercorrelation estimates. Perhaps the clearest indication of interjudge agreement was seen in an examination of the number of judgments in which all eight judges differed by no more than 2 points on the 10-point scales. This is essentially an estimate of the 80% confidence interval. In fact, of the 210 severity estimates made by the eight judges (30 patients, seven scales), only 23 (11%) had a between judge range greater than 2 points and these were spread randomly across the scales. Thus the data indicate that for any given scale, the coefficient of reliability will fall between .74 and .99 depending upon the method used to calculate it, and that eight judges will agree within 2 ppints on the 10-point estimate 89% of the time.

The reliability of the severity ratings was examined (using our averaged estimate) for four categories of the patient population shown in the top section of Table 2. These patient categories include type of dependence, sex, race, and age. Four separate two-way analyses of variance (scale by subgroup) were performed to determine whether there were systematic differences in reliability among scales or subgroups. In each case, there were no significant main or interaction effects ($p > .10$).

The reliability of the severity ratings among subgroups of the judges is examined in the lower section of Table 2. Again, three two-way analyses of variance failed to show evidence of a significant main or interaction effect ($p > .10$) among the severity ratings. This is particularly interesting considering the background of these judges. For example, interviewer 1 was a white female with a Master's degree in social work and very little research experience. She was trained in the use of the ASI especially for this project. Interviewer 3 was a white male research techncian with no clinical experience other than patient admission and follow-up interviews with the ASI. Although the total samples were small, we could find no evidence of any interaction effects between any interviewer and patients of differing age, racial, or drug choice subgroups. Finally, there was no judge or interviewer who was consistently high or low on his ratings of severity on any scale or for any patient group.

Test-retest reliability. Test-retest reliability measures the agreement on *information collected at two separate times.* The test-retest reliability was assessed on a separate sample of 40 patients. An initial ASI interview was performed on a subject and then the subject was recontacted 3 days later and was paid $3 for a second interview. In 15 of these cases the same judge conducted both interviews, while in the remaining 25 interviews a different judge performed the reinterview. The severity ratings as well as the information from the individual questions were compared between interviews, across patients and scales.

Although the data presented above suggested that a group of eight trained judges can agree on the severity of substance abuse patients' treatment problems given the same information, it was important to determine the extent to which patients' self-reports varied over a 3-day period. The 3-day interval was picked because we thought it was long enough to reduce the likelihood of subjects' simply repeating answers from memory, but short enough to reduce the possibility or real changes in the patients' situations.

Our initial inspection indicated very little discrepancy between interviews across all 40 presentations. No single item on the interview showed a discrepancy on more than 25% of the interviews and no single repeated interview showed a discrepancy on more than 10% of the items. Severity ratings produced from the data were virtually identical with all coefficients of concordance equal to .92 or above, even under the two-interviewer condition. Given this smaller amount of variability, we did not think it informative to make statistical comparisons of individual items within the ASI. However, we thought that one important and

TABLE 2
Inter-rater Reliability Coefficients[a]

All patients	N for Ratings	Medical	Employ-ment	Alcohol	Drug	Legal	Family/ Social	Psychi-atric	All Scales
All patients	30	.89	.84	.88	.95	.89	.93	.93	.89
Patient characteristics									
Alcohol dependent	14	.93	.81	.88	.70	.86	.85	.94	.85
Drug dependent	16	.83	.84	.75	.89	.86	.80	.89	.83
Male	23	.91	.82	.86	.94	.85	.84	.91	.88
Female	7	.87	.77	.90	.87	.74	.94	.79	.84
Black	11	.93	.89	.86	.96	.93	.86	.96	.91
White	18	.86	.76	.91	.93	.83	.82	.90	.86
Younger than 30	12	.86	.74	.89	.87	.88	.81	.90	.86
30 or older	18	.90	.81	.90	.90	.86	.86	.91	.87
Judge characteristics									
Among female judges	4	.87	.79	.90	.93	.88	.83	.90	.86
Among male judges	4	.90	.80	.89	.91	.83	.85	.91	.87
Interviewer 1	10	.86	.77	.80	.88	.81	.88	.84	.85
Interviewer 2	10	.91	.80	.86	.85	.80	.91	.84	.85
Interviewer 3	10	.89	.82	.80	.88	.86	.88	.90	.88
Among counselors	3	.83	.81	.79	.84	.85	.83	.91	.84
Among research technicians	5	.88	.81	.86	.90	.87	.82	.89	.86

[a] Coefficients represent the mean of independently calculated Spearman-Brown and average intercorrelation values. See text for discussion.

appropriate test would be a paired comparison of the composite scores that are calculated on each problem area as an overall index of patient status. To this end we used the items from each ASI problem area to calculate a composite score in the standard manner (see *Design of the ASI*) for each interview. These composite scores were compared between interviews, for all scales using the paired *t*-test procedure. There were no significant differences between interviews on any composite score ($p > .10$). This was true for both the same-interviewer and different-interviewer conditions.

Despite the lack of significant differences between repeated interviews, it is important to describe the nature and extent of variability that was present. Based upon the data available and discussions with the interviewers, the variability that did exist was due to three sources. First, the patients had some trouble recalling exact numbers of times, treatments, dollars, etc. There did not appear to be deliberate attempts to distort or misrepresent, but rather, the discrepancies that did occur seemed to be due to legitimate difficulty in recall. A second source of patient variability was seen in the items that asked the patient to rate the extent to which a particular problem bothered or annoyed him or her during the past month. The impression of the interviewers was that patients' perceptions of their problems did change somewhat during the 3-day period, with a tendency toward a lessened sense of severity on the second interview, although this was not statistically significant. A third source of variability was found when a different interviewer conducted the second interview. There were no clear examples of this on any single item or scale and there were no significant differences ($p > .10$) between severity ratings of the two interviewers on any scale. However, there were more times in which items from repeated interviews did not match in the two-interviewer condition than in the one-interviewer condition. Obviously, it is not possible to determine whether this small amount of variability was due to differences in presentation, differences in patient perception during the 3-day interval, or both.

Part II. Validity

Concurrent validity. Concurrent validity measures the extent to which groups which are judged to be different based on a test criterion actually show differences on measures which are clearly related to the criterion. As an assessment of the concurrent validity of the ASI severity ratings, the total patient poulation was divided into LOW, MID and HIGH severity groups based on their ratings in each of the ASI problem areas. LOW severity patients had scale values from 0 through 3, while MID and HIGH severity groups had scale values of 4 through 6, and 7 through 9, respectively. These three groups were then compared on items which were clear indications of problem status in each area. These comparison items were taken from both the lifetime and past-30-days sections of each ASI problem area. The three groups were then compared on each of the items using analysis of variance or χ^2 analyses as appropriate.

The results of these comparisons are presented in Table 3. As can be seen, there were differences in the number of subjects in each of the groups due to differences in the patterns of scale ratings. For example, very few of these subjects had very serious employment problems ($N = 23$), while in contrast most patients had only minor medical problems ($N = 102$). Results of the between groups analyses showed significant ($p = .05$ or less) between group differences in the expected direction on all but one of the comparison measures (which showed a trend [$p < .07$] in the expected direction). These results indicated clear evidence of concurrent validity for the ASI scale ratings and these results replicate our earlier work (see Reference 16) as well as the report of an independent group (see Reference 13).

Discriminant validity. Although the results of our initial tests of validity were quite encouraging, we thought that it would be important to attempt an even more conservative assessment of validity by using a series of previously validated comparison tests as well as our ASI severity ratings and composite scores. The discriminant validity procedure as originally discussed by Campbell and Fiske in their classic paper (4) requires that three conditions be met. First, each ASI problem measure (both the severity rating and the composite score) should be correlated in the appropriate direction with its designated comparison test. Second, each ASI problem measure should be more highly correlated with its designated comparison test than with any of the other tests. Finally, a comparison test should be more highly correlated with its paired ASI problem measure than with any of the other ASI problem measures.

Although the discriminant validity procedure is the most sensitive and conservative estimate of scale validity from a conceptual perspective, there are several practical reasons why it has been difficult to show clear evidence of discriminant validity in other multiscale instruments using the paired comparison test procedure. First, the validity of any scale can be no higher than the product of the reliability of that scale and the reliability of its paired comparison test, when this method is used. Thus a scale with a reliability of .80 validated against a comparison test with a known reliability of .80 will have a validity coefficient of no greater than .64 when this method is used. Despite this caveat, we believed it would still be possible to demonstrate discriminant validity with the ASI since, by even our most conservative measure, all ASI scales had reliabilities of .84 or higher and the majority of

TABLE 3

Concurrent Validity of ASI Severity Ratings

	LOW	MID	HIGH	Significant difference
Medical problems	($N = 102$)	($N = 39$)	($N = 35$)	
Time hospitalized	2	4	8	*
Days of medical problems	3	16	24	**
Employment	($N = 90$)	($N = 68$)	($N = 23$)	
% with trade or skill	62	31	6	*
Days paid for working	9	4	0	**
Alcohol use	($N = 39$)	($N = 70$)	($N = 12$)	
Years problem drinking	3	7	10	**
Times treated	1	3	3	.07
Days intoxicated	4	11	15	*
Drug use	($N = 64$)	($N = 53$)	($N = 64$)	
Years heroin use	0	2	7	**
Times treated	1	1	4	*
Money spent	$10	$380	$980	**
Legal problems	($N = 93$)	($N = 36$)	($N = 47$)	
% on probation/parole	12	23	45	**
Convictions	2	4	6	**
Days committed crime	3	10	17	**
Family problems	($N = 61$)	($N = 89$)	($N = 21$)	
Close friends	5	2	1	*
Days family conflicts	1	7	11	*
Days social conflicts	1	3	9	**
Psychiatric problems	($N = 58$)	($N = 67$)	($N = 56$)	
Times treated	0	0	2	*
% Experienced depression	39	81	97	**
% Attempted suicide	3	12	64	**
Days of psychiatric problems	1	15	19	**

* $p < .05$; ** $p < .01$: by analysis of variance or χ^2 test.

the selected comparison tests had been previously evaluated as highly reliable and valid.

A second, more problematic factor, which has often reduced the discriminant validity of multiscaled instruments, is the lack of independence among the scales and the comparison tests (see Reference 12). Thus, when there are high correlations among scales and/or among comparison tests, it is difficult to show good discrimination among scales and tests. This issue was particularly important in the present study since the finding of high intercorrelations among the ASI severity ratings would make it difficult to determine whether the high reliabilities previously shown were due to the methods used in the interview or simply to the controlling influence by one of the ASI scales (perhaps Alcohol or Drug Use) on the judge's determinations of the other scale values.

Again, despite the potential for this type of influence, we thought that the ASI provided at least the minimal conditions necessary for discriminant validity. For example, we had previously shown that the ASI severity ratings were relatively independent in several populations (see Reference 18), with the highest relationships seen between Psychiatric and Family/Social scales (average correlation .34) and between Drug Use and Legal scales (average correlation .26). We believe that these prior results indicate that the substance-abusing population has a number of problems other than their use of alcohol and/or street drugs and that these problems are not necessarily related to the severity of their chemical use (see Reference 18 for discussion).

As a further test of the degree of interrelationship among ASI problem measures in this population, we again intercorrelated the ASI severity ratings from all 181 subjects who participated in the study. These intercorrelations were generally quite modest (average .15), with the exception of the Psychiatric-Family/Social relationship (.38). We explored these intercorrelations further by subdividing the population into alcoholics/drug addicts, males/females, blacks/whites, and patients from each of the three centers. While there were some differences among these samples in the intercorrelations (due largely to differences in variability within samples), the overall results were quite similar to those seen in the total population. Since we were also interested in the characteristics of our ASI composite measures, we performed the same series of intercorrelation analyses on the same samples and using the composite scores. Again, the results were virtually identical with those seen in the analysis of the severity ratings. Finally, we intercorrelated the severity rating and the composite score for each ASI problem area. As expected, the severity ratings (based upon an interviewer's judgment of problem status) and the composite scores (based upon a mathematical combination of items from the problem area) were correlated at .33 or higher on all scales (average = .38). The full set of intercorrelations is available from the senior author.

Thus, given evidence for relative independence among ASI problem measures and despite the fact of a somewhat higher level of intercorrelation among the battery of comparison tests (average = .34), we thought it was possible to proceed with our examination of discriminant validity in the manner described below.

Procedure

Following their ASI interview at treatment admission, all 181 subjects completed a battery of previously validated paper and pencil tests which had been selected as appropriate comparison measures for each of the ASI problem areas. The testing was completed over a 2-day period and all sessions were supervised by the technician. Subjects were paid $10 for completion of the ASI interview plus the full battery of tests. No subject dropped out before completion.

No appropriate validating instrument was found for the ASI legal problem area; thus we used the total number of arrests and the total months incarcerated as validity indices. The Estes Employability Scale (9) was designed as a measure of employment assets and, unlike any other test, *higher* scores indicate *better* status. For all other comparison measures, problem severity or status liabilities were measured, and *higher* scores indicate *worse* problem status. In an earlier version of this paper we found the Cornell Medical Index (7) to be well correlated with our psychiatric severity measures. Upon inspection we found that it was due to the presence of eight items measuring psychosomatic complaints. Thus, in the present version we have rescored the test but have eliminated these items.

The battery of comparison tests used in the discriminant validity procedure was as follows: medical problem area, Cornell Medical Index (7); employment problem area, Estes Employability Scale (9) and the Employment subscale of the Social Adjustment Scale (SAS) (24); alcohol problem area, Michigan Alcoholism Screening Test (MAST) (23) and the Quantitative Inventory of Drinking Behavior (QIDB) (11); drug problem area, Cohen and Klein Drug Use Scale (5) and the Gunderson Drug Scale (10); family/social problem area, Family and Social subscales of the Social Adjustment Scale (24); psychiatric problem area, Beck Depression Inventory (2) and the Hopkins Symptom Checklist-90 Item (6).

Alcohol-dependent patients. Table 4 presents all intercorrelations for the alcohol-dependent sample (*N*

TABLE 4

Intercorrelations among ASI Problem Severity Measures and Comparison Tests: Alcohol-Dependent Sample (N = 58)

	Cornell[a]	Estes[b]	SAS (Employment)	MAST	QIDB	Cohen	Gunderson	Total Arrests	Months Incarcerated	SAS (Family)	SAS (Social)	Beck	Symptom Checklist-90
Medical severity rating	.44*	−.20	.02	.04	.13	−.06	.10	.10	.03	−.08	−.32*	.16	.13
Medical composite score[c]	.58*	−.24	.14	.11	.08	.02	.15	.12	.07	.02	−.22	.26**	.27**
Employment severity rating	.10	−.49*	.37*	.46*	.01	.26**	.24	.18	.19	.28**	.27**	.40*	.41*
Employment composite score	.14	−.54*	.56*	.47*	.16	.12	.09	.20	.22	.20	.24	.19	.25**
Alcohol severity rating	.02	−.16	.21	.31*	.29**	.13	.07	.14	−.06	.23	.22	.28**	.29**
Alcohol composite score	.16	.24	.21	.42	.61*	.04	.00	−.08	−.11	.07	.07	.33*	.20
Drug severity rating	.01	−.14	−.09	.27**	.14	.58*	.61*	.30*	.13	.13	.18	.21	.15
Drug composite score	.11	−.10	.03	.08	.13	.35*	.39*	.20	.08	.04	.08	.31*	.25**
Legal severity rating	.12	−.26**	.26**	.23	.18	.25*	.37*	.61*	.42*	.19	.18	.07	.18
Legal composite score	.18	−.20	.16	.20	.15	.30*	.32*	.52*	.38*	.14	.13	.20	.30*
Family/social rating	.14	−.12	−.13	.13	.10	.32*	.22*	.12	.03	.39*	.21	.28**	.37*
Family composite score	.06	.19	−.22	.03	.10	.21	.19	.03	−.08	.28**	.16	.17	.12
Psychiatric severity rating	.20**	−.13	−.05	.08	.01	.22	.15	.06	.08	.34*	.25**	.44*	.39*
Psychiatric composite score	.18**	−.12	−.12	−.02	−.03	.13	.17	.07	.06	.27**	.31*	.52*	.47*

[a] For greater test specificity, we removed from this scale eight items measuring psychosomatic complaints.

[b] Higher scores on this test indicate *less* severity. We removed from this scale six items measuring general heath, adjustment, and alcohol use.

[c] See text under *Design of the ASI* for a discussion of composite scores and severity ratings. See text under *Procedure* for a referenced list of all comparison tests.

* $p < .01$; ** $p < .05$.

= 58). The boxed values indicate correlations among comparison tests and the paired ASI problem measures. Discriminant validity is shown when the boxed coefficients are the highest values in their respective row and column. As can be seen from the Table 4 data, there was general evidence of good discriminant validity with the average correlation of the boxed coefficients significantly higher (p = .05 or less) than the average correlation of the row and column coefficients on all ASI problem areas. There was some evidence of overlap between the battery of psychological tests and several of the ASI problem measures, especially the employment and family measures. This is expected since there are some obvious relationships between psychiatric function, employability, and ability to relate with family and friends. The ASI legal problem measures were negatively correlated with employability and positively correlated with greater drug use. These relationships are also explainable on common sense grounds.

Drug-dependent patients. Table 5 presents intercorrelations among ASI problem measures and the comparison tests for the drug abuse sample (N = 123). Again, there was good general evidence for discriminant validity in all ASI problem measures, with significant differences shown between the average of the boxed coefficients and the average of the row and column coefficients on all ASI problem areas (p = .06 or less). As in Table 4, there were the expected relationships between psychiatric, family, and (to a lesser extent) employment measures. Unlike the alcohol abuse sample, there were few significant relationships between the ASI measures of legal status and the battery of comparison tests, with the drug abuse tests being the only exceptions. Inspection revealed a higher overall level of criminal involvement in the drug abuse sample than in the alcohol-dependent patients, due in large part to drug procurement and sales. This greater amount of illegal activity among the drug abusers was pervasive; thus variability was reduced (lowering the correlations) and there were no clear associations with the other problem areas.

It should be noted that there were few really robust relationships seen in the tabled data, even in the case of the comparison relationships (boxed values). This is due in part to lack of independence among the comparison tests (average r = .34) and to measurement differential between the ASI measures and the comparison tests. It must be emphasized that the ASI problem measures have been designed as *general* measures of patient status in each area. However, the majority of comparison tests measured more specific aspects of the patient's status in each area (*e.g.*, depression rather than general psychiatric status). Thus, very high correlations cannot be expected due to the factors previously discussed (12).

In general, the data presented for both samples indicate evidence for discriminant validity. This was

TABLE 5

Intercorrelations among ASI Problem Severity Measures and Comparison Tests: Drug-Dependent Sample (N = 122)

	Cornell[a]	Estes[b]	SAS (Employment)	MAST	QIDB	Cohen	Gunderson	Total Arrests	Months Incarcerated	SAS (Family)	SAS (Social)	Beck	Symptom Checklist-90
Medical severity rating	.31*	-.11	.13	-.03	-.09	-.10	-.13	.15	-.04	-.15	-.04	.14	.06
Medical composite score[c]	.28*	-.14	.06	-.05	-.11	-.16	-.16	-.09	.08	-.09	.05	.08	.04
Employment severity rating	.10	-.36*	.33*	.00	.09	.06	.13	.21**	.22**	.21**	.18**	.24**	.18**
Employment composite score	.11	-.31*	.40*	-.14	-.12	.21**	.11	.22**	.19**	.16	.11	.13	.22**
Alcohol severity rating	.08	-.21**	.18**	.74*	.76*	.07	.20**	.08	-.08	.13	.16	.13	.26*
Alcohol composite score	.07	-.11	.03	.55*	.57*	.04	.27*	-.10	.10	.16	.12	.26*	.26*
Drug severity rating	.14	.10	.06	-.17	-.00	.28*	.36*	.34*	.24**	.03	.07	.21**	.25*
Drug composite score	.16	-.12	.05	-.30*	-.08	.29*	.26*	.26*	1.7	-.11	-.08	.24**	.17**
Legal severity rating	.11	-.10	.12	.08	.09	.20**	.21**	.45*	.48*	.10	.17	.00	-.05
Legal composite score	.06	-.06	.11	-.04	.00	.24*	.22**	.56*	.34*	.08	.19**	-.07	.01
Family/social rating	.08	-.07	.09	.19**	.21**	.05	.14	.01	.06	.25*	.19	.16	.29*
Family composite score	.08	.06	-.03	.06	.13	.02	.11	-.04	.08	.18**	.13	.11	.27*
Psychiatric severity rating	.20**	-.10	.21**	.22**	.20**	-.07	.09	.10	.14	.32*	.22**	.29*	.47*
Psychiatric composite score	.16	-.04	.16	.6	.17**	-.01	.09	.07	.08	.31*	.21**	.38*	.50*

[a] For greater test specificity, we removed from this scale eight items measuring psychosomatic complaints.

[b] Higher scores on this test indicate *less* severity. We removed from this scale six items measuring general heath, adjustment, and alcohol use.

[c] See text under *Design of the ASI* for a discussion of composite scores and severity ratings. See text under *Procedure* for a referenced list of all comparison tests.

* $p < .01$; ** = $p < .05$.

true for both the ASI severity ratings and the ASI composite scores in each problem area. Although we have presented data for just the alcohol and drug samples, we also examined the same comparisons for male and female, black and white, younger and older, and the samples from each treatment center. The data in each case were quite comparable to those presented in Tables 4 and 5. The validity data for the male subgroup and (to a lesser extent) for the three treatment center subgroups gave some evidence for a general relationship between the ASI measures of employment status and the other comparison tests. This was not a significant effect, but we hypothesize that generally, and especially for these subgroups, problems in psychiatric and employment status may have a more general and pervasive influence than even the chemical abuse problems, in determining the overall nature and severity of patients' treatment problems (see Reference 18 for a discussion of this issue).

Discussion

The ASI (15, 16) is a clinical/research instrument which has been in wide use to assess the treatment problems found in alcohol- and drug-abusing patients. Seven problem areas are measured in the ASI. They include medical condition, employment, alcohol use, drug use, illegal involvement, family and social relations, and psychiatric status. In each of these problem areas, patients' objective and subjective reports are used to construct a mathematical composite score and an interviewer rating of problem severity. The 10-point severity ratings have been used as clinical estimates of problem status in treatment planning and referral. The composite measures, like factor scores, have been used as criterion measures to assess patient improvement from admission to posttreatment follow-up (see 14, 17, 20, 21, 26).

Despite the growing use of the ASI and the clear need for such an instrument in the field, the only examination of the reliability and validity of this instrument had been our initial evaluation with a patient sample consisting entirely of male veterans (16). In the present report, we have expanded our evaluation of the reliability and validity of the ASI by administering the instrument to 181 patients from three centers, chosen on the basis of the diversity of their patient populations.

The results of this expanded evaluation suggest three conclusions. First, the ASI is quite reliable. Trained technicians, serving as interviewers, can estimate the severity of patients' problems with an average reliability of .89. Further, this level of reliability was uniformly high for each of the seven problem areas and for subgroups of the patient population divided on the basis of age, race, sex, primary drug problem, and treatment center. These results replicate our original report on male veterans and extend the findings to a greater range of substance-abusing patients.

The consistency of the patient self-report data over a 3-day, test-retest interval was also very reliable. Paired statistical comparisons of the composite measures and the severity ratings showed no significant differences ($p > .10$), even when different technicians performed the repeat interviews. Thus, these data suggest that the reliability of both the patient information and the interviewers' ratings of problem severity are at a very satisfactory level.

A second conclusion from the data is that the seven problem areas are relatively independent. That is, the severity of the "addiction-related" problem areas are not necessarily a function of the severity of the alcohol or drug problem, nor does improvement in one of these areas necessarily mean improvement in any other areas. Again, these data confirm our earlier reports (16, 18, 19) and the results from other large-scale studies (1, 22). The practical implication is that an effective evaluation of substance-abusing patients or substance abuse treatments requires a comprehensive assessment of the full complement of potential patient problems, rather than simply an evaluation of alcohol and drug use (see Reference 18 for a complete discussion).

Finally, the data from the present study indicate that both the severity ratings and the composite scores are valid as general measures of patient status in each of the problem areas. Comparisons of these ASI measures with a battery of previously validated tests indicates clear evidence of discriminant validity as discussed by Campbell and Fiske (4). Again, this discriminant validity was found for subgroups of patients based on age, race, sex, primary drug problem, and treatment. Discriminant validity is the most conservative measure of scale accuracy. In fact, we have also shown evidence of concurrent and predictive validity using the ASI (16, 19, 20) and these findings complement the validity reports on the ASI from two independent studies (13, 21). Taken together, these data suggest that the instrument may be used with confidence across a range of substance abuse patients and treatment centers.

Strengths and Limitations of the ASI

The presented data both here and elsewhere argue for the reliability, validity, and utility of the ASI in general use within the substance abuse field. In fact, we are satisfied in many ways with the instrument. However, we believe it is important to provide additional, critical commentary based upon 6 years of experience developing and using the instrument. Specifically, we have been very satisfied with the information obtained in the problem areas of employment, alcohol use, drug use, and legal status. The interview seems to flow well in these areas, and upon completion there is generally the sense that the interviewer has a realistic appraisal of the patient's status in each of these areas. Many workers who have used the ASI with particular samples of patients have added items to tap specific aspects of a problem area (particularly alcohol use). We have encouraged this, and our experience has been that minor additions have proven adequate for most applications.

The level of information available from the medical and psychiatric problem areas is less detailed and sensitive than from the other areas. Since the ASI was designed for use by a technician and not a physician, we have purposely avoided diagnostic issues and concentrated upon overt symptoms. While the ASI may not detect more subtle problems in these areas, when a problem *is* indicated, there is usually a need for intervention. Thus, although these problem areas are less sensitive, they are reliable, valid as screening assessments, and among the more important problem areas within the ASI with regard to predicting treatment outcome and matching patients to treatments (see References 19, 20).

The family/social area has concentrated upon an assessment of the "conflicts" patients have experienced in their relationships with family and others. Although the ASI does appear to provide a reliable and valid evaluation of *this aspect* of the problem area, this orientation assumes that relationships are (and have been) available, and that it would be "normal" *not* to have conflicts within the available relationships. Workers in this field will recognize that neither of these assumptions is always appropriate within this patient population. The structured format of the ASI and the fixed-choice questions seem adequate or better for assessing the other problem areas, but this format seems less appropriate for the myriad of complex and highly individualized family problems that occur in these patients. We have explored the use of other available measures that are designed to assess this problem area, but have not found a truly adequate instrument. We encourage others in the field to approach this difficult and important problem area by collecting additional information.

It must be remembered that the ASI was designed for use as an interview and not a questionnaire. We have done extensive testing of the ASI under conditions where interviews are performed face to face, over the phone, and where the ASI information has simply been entered on the form. The reliability of the ASI severity ratings drops to approximately .74 in phone interviews and approximately .55 when the information is simply presented in written form. For this reason, and because of serious problems with many patients' reading comprehension, we do not endorse the use of the ASI when administered as a questionnaire or via computer terminal.

It is also important to note that, while considerable attention has been devoted to the problem severity ratings, they are only seven items in a 180-item interview. The remaining information has been quite useful in making treatment plans, assessing outcome of treatments, and predicting treatment response. For these reasons in particular, the Joint Commission on Accreditation of Hospitals has indicated that the ASI is a "model instrument" for satisfying its requirements for "a comprehensive patient admission assessment leading to an individualized treatment plan."[6]

Experience with more than 4000 substance abuse patients over the past 6 years, admitted to both inpatient and outpatient care at these and other centers, indicates that the ASI is applicable to, and even appreciated by, the majority of clients. Unsolicited comments from many patients indicate that the format of the interview encourages the patient to focus upon the individual aspects of his addiction. There have been few negative comments, and the majority of these questioned the uses of the information and who would have access to it. Once assured that the information would not leave the treatment setting, the majority of patients have cooperated. It has been our policy not to force a patient to submit to an interview.

Three subgroups of substance abusers appear to be inappropriate for evaluation by the ASI. Some older substance abuse patients (generally alcoholics) presenting overt evidence of cognitive impairment are sometimes unable to analyze the individual problem areas separately. They may confuse the distinctions between different questions, thereby reducing the validity of the information.

A second subgroup of substance abusers with which we have had little success is a small (but significant) group of younger, generally drug-addicted, patients often having a history of criminal involvement. Many of these patients deliberately misrepresent their objective answers and their subjective patient ratings. We have been able to detect this pattern through verification of objective items and through built-in consistency checks within the ASI. The results of our 6-year experience with ASI interviews, from both alcoholics and drug addicts, show that approximately 5% of all interviews have been discarded for invalid information, and less than 3% of interviews have been poorly comprehended by the patients.

Adolescents younger than 16 years old who are supported by their families form a third group of patients for which the ASI is not an adequate evaluation. The ASI was designed for use with adult or older adolescent populations. Many of the individual items within the interview assume at least the capacity for self-support and adult relationships. While much of the information collected in an ASI interview could be useful in an evaluation of younger adolescents, we must state that a significant proportion of the ASI would not be appropriate for children attending school and residing with parents. We would encourage interested parties to adapt the design and items of the ASI to more effective use with younger populations.

In summary, we have found the ASI to be highly reliable, valid, and easy to use in both clinical and research applications. In addition, other investigators have now reported similar findings in different treatment settings, patient poulations, and research studies. We believe that the design and format of the ASI have provided special advantages in the examination of both substance abuse patients and substance abuse treatments. For example, we have found that reliable subgroups exist within alcohol- and drug-abusing patient populations, each having particular constellations of treatment problems (14, 16, 19); that the psychiatric problems of patients, rather than their alcohol or drug problems, are the most consistent predictors of treatment outcome (14, 19, 26); and that patients can be "matched" to the most effective type of treatment based upon their ASI information (14, 20). In using the ASI to evaluate treatments, we have found that various patients respond differently to the same treatment (14, 17); that specific types of substance abuse treatment have particular effects (14, 20, 26); and that improvement in one treatment problem, even alcohol or drug use, is not well related to improvement in other problem areas (18, 19).

There is not, and will not be, a totally satisfactory instrument to assess what is arguably the most complex health care problem in the world: substance dependence. However, the ASI is now widely used in both clinical and research applications, and despite its limitations, we are quite encouraged by the potential advantages of the ASI in examining important issues such as predicting treatment outcome, comparing different forms of treatment, and "matching" patients to treatment.

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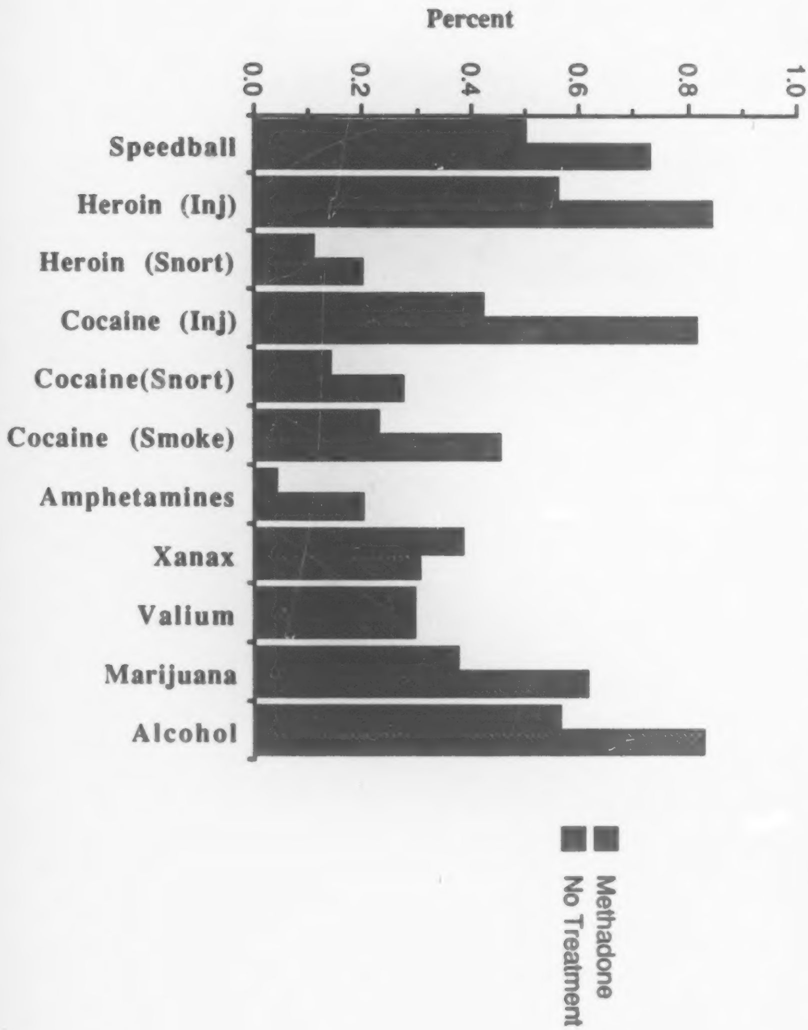
Subject Characteristics

Age	In-Tx (N=371)	Out of Tx (N=98)
Average	39.4	38.4
SD	7.4	8.8
Race*		
Black	209 (57%)	76 (78%)
Latino	28 (8%)	5 (5%)
White	119 (32%)	15 (15%)
Other	11 (3%)	2 (2%)
Gender*		
Male	274 (72.5%)	83 (85%)
Female	104 (27.5%)	15 (15%)
Marital Status		
Single	161 (42.5%)	52 (54%)
Married	87 (23%)	15 (16%)
Separated	59 (15.6%)	18 (19%)
Divorced	54 (14.2%)	7 (7%)
Widowed	18 (4.7%)	4 (4%)

Support	IN	OUT
Monthly Income	$500	$350**
% Employed	28%	5%
Past Yr. Employment	53%	59%
Diploma	56%	58%
Veteran	14%	20%
Food Stamps	75.5%	58%

Drug Use	IN	OUT
Average Age of First Use		
Alcohol	15	14
Marijuana	17	16
Heroin	20	20
Cocaine	26	27
Drug Use During Past 30 Days		
(% using Several Times or More Each Week)		
Speedball	26.4%	43%***
Heroin (Injected)	28.8%	64%***
Heroin (Snorted)	4.8%	4%
Cocaine (Injected)	20.8%	58%***
Cocaine (Snorted)	4.3%	12%**
Cocaine(Smoked)	8.9%	23%**
Amphetamines	.3%	6%**
Xanax	16.1%	11%
Valium	9.7%	6%
Marijuana	16.6%	20%***
Alcohol	26.4%	54%***
No Use of Any Drugs (excluding alcohol) during Preceding 30 Days	12.4%	1.5%

Rate of Drug Use Among Opiate Users In and Out of Methadone Treatment



HIGH RISK ACTIVITY	In	Out
Been to Shooting Gallery Past 30 Days	29.3%	55%***
Been to a Crack House Past 30 Days	11.9%	31%**
Bought Needles in Shooting Gallery	28.1%	48%***
% Using New Needles All the Time	33.4%	10.9%***
Hard to Get New Needles	15.6%	25%*

Needle Use	In	Out
Injected	78%	96%***
Shared Needles	35%	74%***

HIGH RISK ACTIVITY	In	Out
Had sex to get drugs	5%	9%
Given drugs to get sex	13%	33%
Paid money for sex	7%	26%
Been paid for sex	6%	7%
Had sex with someone who had AIDS	3%	2%
Shared with someone who had AIDS	4%	3%
Been Tested for HIV	53%	32%

Drug Risk	IN	OUT
No injection	24%	5%
Injection but no sharing	47%	27%
Sharing 1 or 2 times	11%	12%
Sharing 3 - 6 times	12%	26%
Sharing 7+ times	7%	31%

Sex Risk	IN	OUT
No sexual activity	23%	12%
Sexual activity with condom use	11%	11%
Sexual activity with one partner and no condom use	42%	31%
Sexual activity with multiple partners and no condom use	24%	46%

Drug Treatment	In	Out
Average age of 'Awareness'	23	24
Average age of first treatment entry	27	27
Average number of treatment entries	4.8	3.5
Average methadone dose	42.3 mgs.	NA
Average length of time in treatment	33 mths.	

SUBMITTED FOR THE RECORD BY GEORGE E. WOODY, M.D., PHILADELPHIA VA MEDICAL CENTER

INTRODUCTION

With the rapid spread of AIDS among IV drug users, particularly opiate addicts, the need for an effective and acceptable form of drug abuse treatment is even more important than in years past. Methadone maintenance has been an inexpensive and well-accepted (by patients if not society) form of treatment for opiate dependence and many have called for a rapid expansion of methadone programs. *How* this expansion should occur is far from decided, and often controversial: Should *rehabilitative services* (counseling, medical, psychiatric, and vocational interventions) be *eliminated*, using the resulting funds to create more treatment slots in programs offering 'methadone alone'? Or would removal of these rehabilitative services drastically *reduce the effectiveness of the pharmacologic intervention*, rendering it nearly useless in the battle against intravenous drug use and AIDS? Further, can it be demonstrated that *increased rehabilitative services* would show significant reductions in opiate use, non-opiate use, and illegal activity during their treatment (Hubbard and Marsden 1986; Sells et al. 1979). Further, it is equally clear from the body of published work in this area that the majority of methadone maintained patients have a longer and more serious history of substance abuse (as well as other problems) than patients treated in other modalities (eg. Drug Free Outpatient Treatment or Inpatient Therapeutic Community Treatment)(Hubbard and Marsden 1986; Sells et al. 1979).

What Is the Most Effective Way to Expand Methadone Treatment Services?

The recent spread of AIDS in the drug using population has led to the call for rapid expansion of funded methadone treatment slots. There are two views about how such an expansion should occur, based largely on different concepts of the 'active ingredients' in methadone maintenance treatment. *The first perspective holds that methadone* ***alone****, as a pharmacologic agent which blocks opiate withdrawal and (through cross -tolerance) opiate euphoria , is the primary 'active ingredient' in methadone maintenance treatment, and the one directly responsible for patient improvements. Counseling requirements and rules and regulations presently associated with this modality are viewed as probably useful but costly, having the unwelcome 'side-effect' of reducing the total number* *of available patient slots.* Proponents of this 'methadone alone' view argue for the elimination of a minimum counselor-patient ratio requirement (now 1 to 50), and for further reduction in the number of urine specimens required by the treatment programs (now 1 per month). With these more liberalized criteria, it is argued, more potential clients could be be given methadone and in turn, the risks for continued drug use, crime, and AIDS could be reduced. Psychiatric, medical, vocational and other rehabilitative services (already scarce or non-existent in most programs) are not viewed as cost-effective. Adding such services, it is argued, would cost substantially more than 'methadone alone', but would not lead to measurably better performance on factors closely related to AIDS: reduced intravenous drug use, reduced needle-sharing, reduced AIDS-risk behaviors, reduced incidence of AIDS itself, and the associated medical costs.

The opposed view argues that ***methadone alone**, despite its pharmacologic value, is **not** the only 'active ingredient' in methadone maintenance treatment, and, without a context of adequate **administrative support, counseling, urine monitoring and rehabilitative services**, is very unlikely to lead to a reduction in drug use and AIDS-related target behaviors.* From this perspective, the poor performance of many ongoing methadone maintenance programs (*even under current* *counseling and urine guidelines)* can be traced to lack of adequate staffing, administrative, and rehabilitative services. Minimal service programs do not have the resources needed to reduce the proportion of patients who loiter, divert their methadone, continue use of illicit drugs, and even 'deal drugs' near the program site – making the programs unwelcome in most communities (Wrangle 1988) and the treatment modality itself controversial (Cummings 1979; Newton 1979), even among many substance abuse professionals. Adding more 'methadone only' treatment slots, the argument goes, would only increase community problems and further tarnish the image of methadone as a treatment modality. Image concerns aside, a feared outcome of expanded 'methadone only' treatment could be a dramatic increase in all the problems outlined above, with little or no beneficial impact on intravenous drug use, AIDS-risk behaviors, or AIDS. *In this view, methadone should be administered under close counseling supervision, with urine contingencies and with a full program of supportive services, for it to achieve its full value as a tool for reducing drug use and AIDS risk.*

ARE THERE NECESSARY MINIMAL CONDITIONS FOR METHADONE TO BE EFFECTIVE?

If methadone itself is the only 'active ingredient' in reducing intravenous opiate use, then rates of opiate use among demographically similar patients across different programs should be similar. Several pieces of clinical evidence now emphatically suggest this is *not* the case. In the course of performing an evaluation of professional psychotherapy as an adjunct to methadone maintenance (Woody et al.1983) we had the opportunity to observe several programs and the patients in them. Despite relatively small differences in demographic, background or current status measures among the patient samples from these different programs, we have seen *dramatic differences in such fundamental outcome measures as proportion of opiate-positive urines, number of visits to the program, average methadone dose, etc.* An example of the size of these differences is shown below, illustrating the proportion of opiate-positive urines for patients in two community programs as well as in our own VA program. As can be seen these differences are quite large and because of small differences seen among the patient samples, suggest that there are basic programmatic differences that account for the observed performance differences.

These observations are similar to those of Dr. John Ball in his three-year evaluation of methadone treatment in six different programs from three eastern cities (Corty and Ball 1987; Ball et al. 1988). In general, the patients treated in these programs were quite similar in terms of their demographic

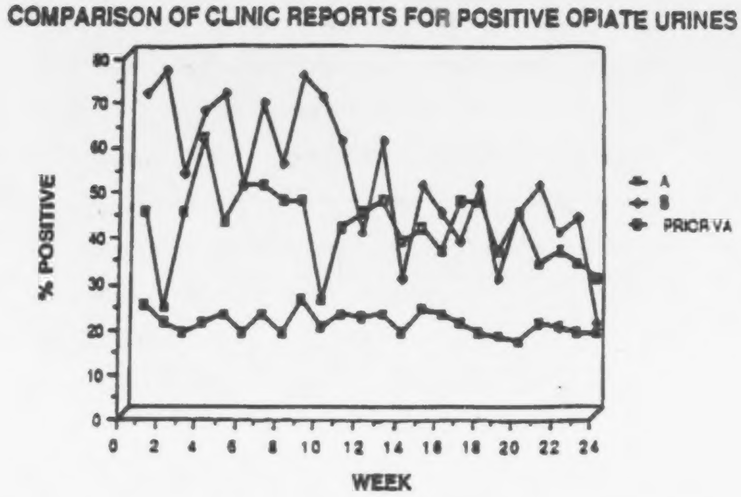


Figure 1. Rates of opiate positive urines in the Philadlephia VA methadone maintenance program and two community methadone maintenance programs over a 6-month (24 week) study period.

characteristics and treatment problems at the time of admission to methadone maintenance across the different geographic sites surveyed. *In contrast, the data gathered have revealed striking differences in patient performance, depending on the program. Rates of current intravenous drug use ranged from less than 10 % to more than 50 % (compare Programs A, E and F; respectively, in Figure 2 below), and rates of needle-sharing showed a similar pattern.* Though all these programs administered methadone, the effectiveness of this treatment ranged from impressive to almost non-existent. The programs differed widely on such important parameters as dose (one program had an average methadone dose of 20-25 mg while other programs averaged 45-50 mg), medical coverage, use of ancillary psychotropic medications, uniformity of enforcement of rules, caseloads of counselors, informed psychiatric input into decision-making processes, quality of inservice training and physical facilities. Importantly, several of these *program variables* showed a predictive relationship to treatment outcome.

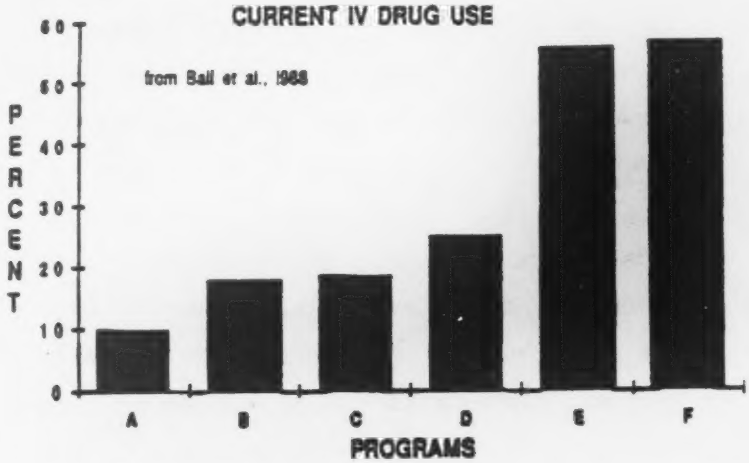


Figure 2. Rates of current intravenous drug use across six different methadone maintenance programs, two from each of three U.S. cities.

The implications of these data are quite important with regard to the two previously described views on expanding methadone treatment. *Clearly, simply administering methadone does not by itself guarantee clinical improvements or reduced AIDS risk. On the other hand, when necessary minimum conditions are met, this treatment modality can lead to dramatic and sustained improvements, many of which (reduced intravenous drug use, reduced needle sharing) are directly relevant to the spread of AIDS . Thus, identifying the programmatic factors and the minimal administrative conditions necessary for effective methadone treatment are crucial steps in improving methadone maintenance and in helping to contain the AIDS epidemic.*

Determining the "Active Ingredients" in Methadone Maintenance

We have recently begun a set of studies designed to help determine the "active ingredients" of methadone maintenance treatment. The full design and procedures for these studies are described elsewhere (McLellan et al. l989b). The basic design compares *three different levels of methadone services* (**Minimum, Basic** and **Enhanced Methadone Maintenance**) within each of two *explicitly different types of methadone programs* (a hospital-based, medically-oriented program at the Philadelphia VA; and a nearby community-based, social service oriented program) for both newly-admitted and in-treatment samples. Study participants in each program setting are initially stabilized on a modal dose of 40-45 mg methadone and then randomly assigned to one of *three different levels of methadone treatment services provided and prospectively evaluated over a six-month period:*

A) *Minimum Methadone Maintenance (MMM)* offers blocking doses of methadone, plus emergency counseling and referral services; but no regular counseling, no privilege or service contingencies based on urine results and no extra services such as family or employment counseling.

B) *Basic Methadone Maintenance (BMM)* offers blocking doses of methadone, plus regular, supervised counseling and referral services using weekly urine screens as the basis for contingency management of the patient; but no extra services such as family or employment counseling. A central feature of *BMM* is *drug counseling*, shown by Woody and by McLellan (Woody et al. 1987; McLellan et al. 1989a) to be a *particularly significant aspect of methadone maintenance treatment*, with the ability to markedly enhance or detract from the other aspects of the program (eg., methadone dose, rules and regulations, etc.).

C) *Enhanced Methadone Maintenance (EMM)* offers blocking doses of methadone, plus regular, supervised counseling and referral services using weekly urine screens as the basis for contingency management of the patient; plus regular additional services including *medical/psychiatric care, social work assistance, family therapy and employment counseling* designed to develop job-seeking and job-holding skills. The selection of extra services such as family therapy and employment counseling was based on the recognition that most methadone maintenance patients *have multiple problems which, if untreated, can undermine the effectiveness of the pharmacologic intervention.* The psychiatric problems (Rounsaville et al. 1982), Khantzian and Treece 1985) and Woody et al. 1983), family problems(Stanton 1979; Stanton et al.1982), and poor job-seeking skills (Platt and Metzger 1985; Metzger and Platt1988) of methadone maintenance patients have been well-documented. Regardless of the original relation between these problems and the opiate addiction, it is clear that the presence of these additional problems significantly affects the course and overall results of treatment (Hubbard and Marsden 1986; Sells et al. 1979; McLellan et al.1982, McLellan et al. 1986). *It is therefore possible that a more enhanced and expensive program, providing effective treatment for the medical, psychiatric, family and employment problems of these patients may actually be more* ***cost-effective*** than the less expensive programs; ***particularly If*** this enhanced treatment is significantly more effective in reducing AIDS-risk behaviors and more capable of effecting greater social rehabilitation and productivity with corresponding reductions in crime, welfare and the utilization of expensive medical care services.

All patients are evaluated using a battery of instruments at the start of treatment, at three months and at six-months during treatment, as well as six-months following their intervention (McLellan et al. l989b). Additional during-treatment measures include attendance, drop-out, health care utilization and urine screening records. Major post-treatment outcome measures include drug use (particularly IV drug use), employment, crime, health care utilization, high-risk- for-AIDS behaviors and the costs of care delivered to each patient during treatment.

Of all the outcome measures listed above, perhaps one of the most clinically significant is the number of patients in each treatment level who require "protective termination" from the project due to an unacceptable level of illicit drug use. Ethically, we did not want study patients to be at any greater risk for HIV exposure than other patients receiving standard methadone treatment at our clinic. Therefore, we developed a set of "safeguards", which, if exceeded, result in the patient's termination from the treatment project and referral to "treatment as usual" at the same site. The "safeguards" are as follows:

1) A total of eight opiate-positive urine reports or four opiate-positive urines in a row, during the course of the 24-week intervention.

2) A total of twelve cocaine-positive urines or six cocaine-positive urines in a row, during the course of the 24-week intervention. **Note:** Cocaine use is not always IV, even in these patients, and is considered somewhat less serious than opiate use, thus the decision to allow slightly more cocaine use prior to requiring termination.

3) Three or more medical or psychiatric emergencies, necessitating inpatient referral or an intensity of treatment inconsistent with the assigned level of services.

Termination from the study means, essentially, that the level of methadone services received by the patient was not sufficient to reduce illicit drug use and to offer protection from AIDS.

Though data collection is still in the very early stages, a striking pattern of results has already begun to emerge. Within both programs, the *number of patients requiring "protective termination" from the study is by far greatest in the MMM group.* As shown in **Figure 3** below, more than half the patients in the MMM group have already required "protective termination", while *none of the patients in the EMM* have exceeded the described safeguards. *Simply put, the level of* *services in the Minimum Methadone Maintenance intervention failed to meet the minimum conditions necessary for effective methadone maintenance for more than half of the patient sample.* Most of the terminated patients in the MMM group met criterion for termination within only eight to ten weeks of entry into the study -- during which they continued to use illicit drugs, usually opiates and cocaine. Finally, these numbers may

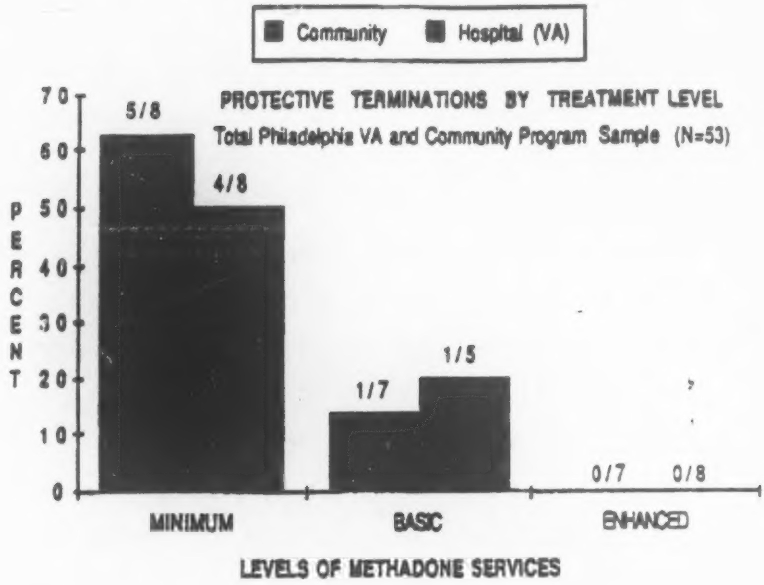


Figure 3. Percent of patients requiring protective termination from three different levels of methadone services across two different methadone maintenance programs

actually *underestimate* the proportion of patients eventually requiring termination, since some of the patients included in these preliminary data have not yet completed 24 treatment weeks and may yet require protective termination.

SUMMARY

Though methadone maintenance is a treatment modality with the demonstrated ability to reduce intravenous drug use and subsequent AIDS risk, methadone maintenance programs vary widely in their effectiveness: demographically similar patient samples show profound improvements in some programs and little change in others. This suggests that programmatic factors, rather than patient variables or sheer availability of methadone, may be important 'active ingredients' in effective methadone maintenance. The AIDS epidemic has led to the demand for increased availability of methadone, with suggested elimination of counseling, urine contingencies and other rehabilitative services in an effort to fund additional 'methadone only' treatment slots. The data reviewed here, including preliminary results from a study examining the effectiveness of 'minimal' methadone services, suggest that merely *increasing availability of methadone in the absence of administrative, counseling and rehabilitative services may not adequately protect the majority of patients from continued drug use and the risk of AIDS.*

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Is Treatment for Substance Abuse Effective?

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• Few studies have assessed adequately the effectiveness of alcohol and drug abuse treatments using an appropriate range of reliable outcome measures, a representative sample of alcohol and drug abuse treatment modalities, or more than one perspective on treatment effectiveness. This article evaluates substance abuse treatment using a sample of 742 patients treated in six programs and evaluated at six-month follow-up. The following three major questions were addressed: (1) do patients improve following treatment; (2) are improvements confined to alcohol or drug use, or are they more pervasive; and (3) are these improvements a result of treatment? The results indicated significant and pervasive improvements in virtually all areas for both alcoholics and drug addicts. Major changes were seen in alcohol and drug use, employment, criminal behavior, and psychological function. Patients undergoing long-term treatment showed greater improvement and better six-month outcomes than those undergoing short-term therapy on 12 of 18 criteria. The data provide evidence for the therapeutic benefit of substance abuse treatments.

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RECENTLY there have been serious challenges to the effectiveness of alcohol and drug abuse treatments, and the impression has been conveyed that their benefits are insubstantial.[1,2] The important question is: What standard of effectiveness shall we accept when there are several reasonable alternatives offering potentially different estimates of treatment worth? For example, is it adequate to know that patients' alcohol or drug use is reduced significantly after substance abuse treatment? The public, the press, and the funding sources have come to expect that patients will also show increased employment, better physical and mental health, and corresponding decreases in hospital utilization, illegal activity, and dependence on welfare after treatment. How realistic are these expectations?

The data derive from our cooperative evaluation of substance abuse treatment funded by the Veterans Administration, the design of which has been described elsewhere.[3] In this study we were able to apply a comprehensive and uniform method of data collection[4] to a sample of 742 male veterans who were alcohol and drug abuse patients, at the time of admission to treatment and again at the six-month follow-up point. The following three specific evaluation issues were examined: (1) do patients improve after substance abuse treatment; (2) are improvements specific to the target symptoms of alcohol and drug use, or are they more pervasive; and (3) to what extent are improvements due to the effects of treatment?

METHODS

Subjects

All male veterans who were admitted for alcohol or drug abuse treatment at either the Coatesville or Philadelphia VA Medical Centers during 1978 were eligible for the study. There were no significant differences in demographic or background characteristics between patients in the two hospitals, and approximately 90% of all subjects were Philadelphia residents. There were no treatment admission criteria other than eligibility for veterans' benefits. Approximately 80% of drug patients were heroin addicts, averaging six years of daily use. The remaining drug abusers reported regular use of amphetamine, benzodiazepines, or hallucinogens. Alcohol abusers averaged eight years of problem drinking, defined as intoxication three or more times per week.

We evaluated 879 male veterans initially who were admitted to alcohol (N=554) or drug abuse (N=325) rehabilitation programs at the Coatesville or Philadelphia VA Hospitals during 1978, and who remained in rehabilitation treatment for at least five days.[3] Seventeen percent of the alcoholics dropped out of treatment within five days as compared with 13% of the drug addicts. This difference was significant ($P<.05$) although there were no significant differences in dropout among the three individual alcohol or the three individual drug programs. We were able to contact approximately 85% of the remaining patients six months after admission to treatment, so complete data were available for 742 subjects (460 alcoholics and 282 drug addicts).

Treatment Programs

The substance abuse treatment network of the VA in the Philadelphia area consists of four inpatient (two alcohol, one drug, one combined) programs at the Coatesville VA Medical Center, plus outpatient alcohol and drug abuse clinics at the Philadelphia VA Medical Center. Once

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admitted to substance abuse treatment programs at either hospital, patients were assigned to one of the six rehabilitation programs on the basis of their personal requests, the clinical judgment of the admitting staff, administrative considerations (eg, bed census), and simple chance.

Following are brief descriptions of the programs; for more complete information see Gottheil et al[6]:

Alcohol Treatment Unit.—Is a 60-day therapeutic community based on the principles of Alcoholics Anonymous (AA). The staff conducts small-group therapy four times weekly.

Fixed Interval Drinking Decisions.—Is a research program designed to examine and treat alcoholism in the presence of alcohol. The six-week treatment cycle consists of two, one-week alcohol-free periods, and a four-week drinking-decisions phase during which 60 mL of 80-proof alcohol is available, and the patients have the opportunity to decide whether or not to drink. Group and individual therapy are offered daily.

Combined Treatment.—Is a short-term (45-day) program that delivers intensive addiction management therapy to both alcoholics and drug addicts. Treatment is based on principles of AA or Narcotics Anonymous with ancillary individual therapy and educational material.

Drug Abuse Rehabilitation.—Offers personal and social treatment in a 60-day program designed to "habilitate" the patient to society using individual and group psychological therapy, educational and vocational counseling, and the social structure of a self-governing therapeutic community.

Alcohol Outpatient.—Is a variable-length treatment program that concentrates on the medical, psychological, and social problems of the outpatient alcoholics. Therapeutic goals include alcohol abstinence through problems associated with alcoholism.

Methadone Maintenance.—Offers methadone maintenance, in combination with a full program of psychiatric and social-work counseling. Chemotherapeutic and individual psychotherapy interventions are employed to treat associated psychological problems of these patients.

There were of course ideological and methodological differences in the treatment delivery of these programs. We have examined the specific differences in six-month outcome among the programs, and the particular patient and treatment factors that were most associated with optimum outcome in each.[7] While we did see evidence for potential improvement in outcome by matching particular types of patients to the specific programs, there was no evidence for any general outcome superiority in either the alcoholic or drug addict patients or from any single treatment program. Therefore, this article is concerned with the general effectiveness of substance abuse treatment across the individual treatment programs sampled and more specific program effects are reported elsewhere.[7] All conclusions reported pertain to all the individual programs as well as the total population.

Table 1 — Background Characteristics at Admission for Treatment

	Alcoholics	Drug Addicts	Total
N	480	262	742
Age, yr	42§	31	38
Black, %	39§	52	43
White, %	60§	47	56
Education, yr	11.2	11.7	11.4
Skill or trade, %	42	40	41
Employed in past yr, %	38	38	37
Criminal convictions	2§	6	3
Incarcerated, mo	7§	16	10
Married, %	23	24	23
Living alone, %	26§	17	21
Prior alcohol or drug treatment, %	6	5	6
Problem alcohol use, yr	13§	3	9
Regular opiate use, yr	0§	7	2
Regular nonopiate use, yr	1§	4	2

§$P<.01$ by paired t test.

PROCEDURE

Admission

The admission and follow-up evaluations were based on data from the Addiction Severity Index (ASI).[8] The ASI is a structured, 30- to 40-minute clinical research interview designed to assess problem severity in seven areas commonly affected by addiction. These areas include alcohol and drug use and medical, legal, employment, family, and psychological problems. In each of the areas, objective questions are asked, measuring the number, extent, and duration of problem symptoms in the patient's lifetime and in the past 30 days. The patient also supplies a subjective rating of the recent (past 30 days) severity and importance of each problem area. Sets of objective and subjective items from each of these areas were standardized and summed to produce composite measures that provided reliable and valid general estimates of problem severity,[8] both at the time of admission and at follow-up.

Follow-up

All follow-up evaluations were done through ASI interviews between an independent research technician and the patient. No information from secondary sources was used and all data were monitored closely to preserve confidentiality. The validity of the follow-up data in this study was monitored through built-in consistency checks within the ASI and through spot checks on subsamples of our outpatient population, assessing the ASI data against urinalysis results, pharmacy records, and criminal justice system records. We found less than 5% inconsistency, and similar findings have been reported by other investigators studying the validity of patients' self-reports.[12]

RESULTS

There were clear differences between the alcoholic and drug addict (Table 1) samples in age ($t=20.4$, $df=637$, $P<.01$) and radical composition ($\chi^2=27.4$, $df=1$, $P<.01$), while they were similar in years of education.

Admission data from ASI interviews indicated that the average patient started treatment with severe problems of alcohol abuse, drug abuse, or both, and moderately severe employment, family, and psychological problems. The alcoholics presented more severe medical problems, while the drug addicts showed more severe legal and employment problems. Although the samples did not differ quantitatively in the severity of the other problem areas, the nature of their particular problems within each area was generally quite different.

Patients spent an average of 51 (SD=17) days in rehabilitation treatment and there was no significant difference between the drug and alcohol group samples ($P>.10$). During

Table 2.—Change in Alcoholics and Drug Addicts From Admission to Six-Month Follow-up

	Alcoholics (N=480)		Drug Addicts (N=282)	
Criterion Composites*	Admission	6-mo Follow-up	Admission	6-mo Follow-up
Medical composite	13.8	12.8	9.4	7.0
Medical problems, days	9	8	8	8
Employment composite	10.3§	−3.8	12.1§	−2.9
Days worked	6§	10	3§	11
Money earned, $	210§	318	80§	308
Alcohol composite	38.4§	16.2	18.1†	13.4
Drinking, days	13§	6	8	7
Intoxicated, days	10§	3	5†	3
Drug composite	4.0†	1.8	27.2§	5.8
Opiate use, days	0.6	0.1	12§	4
Nonopiate use, days	1.0	0.4	8†	2
Legal composite	2.2	1.1	21.9§	9.4
Crime, days	1	0.3	9†	3
Illegal income, $	15	11	394§	91
Family composite	10.9§	4.3	14.2§	9.6
Family problems, days	7§	3	10§	6
Psychological composite	13.1†	9.5	14.1†	9.8
Psychiatric problems, days	10§	5	11§	7

*All criteria were measured during 30 days before admission and before six-month follow-up.

†$P<.05$.

§$P<.01$.

treatment, patients received an average of 26 (SD=7) individual and 24 (SD=7) group therapy sessions. Again, no significant differences were found between the samples on either of these measures ($P>.10$). However, 65% of the alcoholic patients received a favorable discharge from treatment, as compared with only 51% of the drug addicts.

ADMISSION AND FOLLOW-UP COMPARISONS

One direct assessment of treatment outcome is a comparison of patient status measured at fixed intervals before and after treatment. In the present study, we compared patients' status during the 30-day period before admission and before the six-month follow-up, using a standard paired *t* test statistic. These within-group comparisons are presented for all seven criterion composites and for selected single-item criteria in Table 2. Greater scores on the composite measures indicate greater problem severity. While the absolute values of these composites (like factor scores) hold little meaning, the significance of the admission to follow-up changes are useful indicators of general improvement.

As can be seen in Table 2, there was clear evidence of significant improvement in most areas for both samples. The improvement was most significant in the target symptoms of alcohol and drug use, but was also considerable in the areas of employment and psychological function. One exception to this general improvement was the area of medical status. While there was a tendency toward problem reduction in this area for both groups, neither showed significant improvement.

BETWEEN-GROUP COMPARISONS

In an experimental design, the extent to which nontreatment factors influence patient change can be assessed through a comparison with an untreated control group. This type of design was not feasible for the present study, yet we were concerned that the amount and extent of change seen in the treated groups was inflated by nontreatment factors. We considered a between-groups comparison between the treated groups and those patients who had dropped out of treatment during the first five days of rehabilitation. This type of comparison has been reported previously,[7,8] but an examination of these dropout patients indicated that they had generally more severe problems at admission and clearly worse prognoses than our treated groups. Thus, the comparison appeared artificial and served only to distort further the actual effect of the treatment by providing a "straw" comparison with a poor-prognosis group.

To develop a more rigorous assessment of the actual treatment effect, we attempted to draw a meaningful comparison group from our larger population. Ideally, we wanted patients who had been comparable in pretreatment status and during-treatment performance, but had received less treatment. To this end, we chose all patients from the larger sample who had received more than five but fewer than 15 days of rehabilitation treatment, and who had received a favorable treatment discharge. While this short-term (ST) group may not be considered a control group in the conventional sense, the 98 alcoholic and 57 drug-addicted patients who met the ST criteria provided an appropriate assessment of cumulative treatment effects on several grounds. For example, ST patients had been assigned to the rehabilitation programs in the same manner and in the same proportion ($\chi^2=2.14$, $df=5$, $P>.10$) as the long-term (LT) groups. Second, the ST patients had performed as well as, or better than, the LT patients during treatment, as evidenced by their favorable discharge status. Finally, comparisons of admission status disclosed no significant differences among the ST and LT patients in the areas of age, education, or racial distribution. In fact, the ST patients had significantly fewer previous treatments ($P<.05$) and significantly lower severity ($P<.05$) in the family and social problem area. Thus, the comparison group selected was arguably conservative and adequate for estimating the actual effects of treatment.

Alcoholics

Within-group comparisons for both the ST and LT alcoholic groups are presented in Table 3. Paired *t* tests were again calculated for all criteria to assess the significance of the changes. As can be seen, the LT patients showed a greater number of significant improvements at a generally higher level of significance than did the ST patients. However, the ST patients also showed several areas of significant improvement.

Despite the similarity in pretreat-

Table 3.—Alcoholics

	Within-Group Comparisons				Between-Group Comparisons
	Long-term (N=[illegible])		Short-term (N=[illegible])		
Criterion Composites*	Admission	6-mo Follow-up	Admission	6-mo Follow-up	Posttreatment P Value†
Medical composite	14.0	12.2	12.6	13.0	. . .
Medical problems, days	10	6	6	6	. . .
Employment composite	10.3§	−4.3	10.1‡	−2.7	<.01
Days worked	6§	11	7	9	<.05
Money earned, $	209§	394	215	264	<.01
Alcohol composite	37.1§	14.2	39.9§	20.6	<.01
Drinking, days	12§	5	14§	10	<.01
Intoxicated, days	9§	3	10§	3	. . .
Drug composite	3.8§	0.5	5.0	2.8	<.05
Opiate use, days	0.6	0	0.8	0	. . .
Nonopiate use, days	1.0§	0.2	1.6	0.3	. . .
Legal composite	2.4‡	0.6	2.0	1.6	<.05
Crime, days	1	0	1	2	. . .
Illegal income, $	17‡	9	14	12	. . .
Family composite	11.6‡	6.0	7.4‡	3.8	. . .
Family problems, days	8	6	4§	2	. . .
Psychological composite	13.4‡	8.9	12.5	11.7	<.01
Psychiatric problems, days	11§	4	10	7	<.01

*All criteria were measured during 30 days before admission and before six-month follow-up.
†Covariates were age, race, number of previous treatments, and pretreatment score.
‡P<.05 (Student's paired t test).
§P<.01 (Student's paired t test).

ment status of the LT and ST groups, we thought it would be important to adjust statistically the two samples on all relevant variables before making a direct comparison of their follow-up outcomes. To this end, we performed analyses of covariance on all follow-up criteria using age, race, number of previous treatments, and the pretreatment criterion score as covariates in each analysis (last column, Table 3). As can be seen, the LT group showed significantly better employment, alcohol use, drug use, legal status, and psychological function than the ST group, despite some significant improvements by the ST alcoholics. No significant between-group differences were shown in the areas of medical health or family relations.

Drug Addicts

Within-group comparisons for the LT and ST drug addict groups are presented in Table 4. As in the case of the alcoholic sample, the LT drug addict group showed a greater number of significant within-group changes at a higher level of significance than the ST drug addicts. There is an even greater disparity between these groups than between the LT and ST alcoholics. The LT group showed significant improvements in most areas, but especially in employment and drug use. The ST group showed significant improvement in the areas of employment, drug use, and psychological function, no significant change in alcohol use or medical status, and a trend toward poorer outcome in legal status and family relations.

We again made direct comparisons of the six-month outcome data for the two groups using analysis of covariance to adjust statistically for differences in age, race, number of previous treatments, and admission scores on each criterion. The LT addicts showed significantly better posttreatment outcomes than the ST group in all seven criterion areas (last column, Table 4). The magnitude of difference between the two groups was greatest in the areas of legal status and drug and alcohol use, but moderate differences were also seen in employment, family relations, and psychological status.

COMMENT

We examined the results of substance abuse treatment in a sample of male veteran alcoholics and drug addicts treated in our rehabilitation programs. Highly reliable composite measures were recorded at treatment admission in seven areas commonly affected by addiction. The same measures were again recorded on an 85% follow-up sample six months later, by independent technicians. Results provided data for three different evaluation issues.

Do Patients Improve After Substance Abuse Treatment?

Based on our within-group paired comparisons of admission and follow-up status, the answer is unequivocally "yes" for both the alcoholics and the drug addicts. Highly significant improvements were seen in both our composite criteria (indicating general problem status), and in the single-item measures.

Are Improvements Specific to Alcohol and Drug Use, or Are They More Pervasive?

Results of both the within- and between-group comparisons indicated significant improvements in most of the seven criterion areas for both samples. The most significant improvements were shown in the target areas of alcohol and drug use, but highly significant improvements were also shown in the areas of employment and family and psychological status for both samples. In addition, the drug addict group showed significant improvement in legal status. In practical terms, these improvements translated to a 54% reduction in the number of days drinking, a 67% reduction in the number of days intoxicated, and a 151% increase in earned income for the alcoholics. Further, 41% of these patients were abstinent from alcohol during the 30 days preceding follow-up. The drug addicted patients showed a 67% reduction in opiate use, a 50% reduction in stimulant use, a 67% decrease in crime days, and a 396% increase in earned income. Forty-eight percent of the patients were drug free (excepting alcohol and marijuana) during the 30 days preceding follow-up. Thus, the evidence here and from other studies[1-4] suggests that the major improvements following substance abuse treatment are in alcohol and drug use, but that there are several other areas that show moderate to major changes.

Perhaps the only clear exception to this general improvement was the area of medical status or physical

Table 4.—Drug Addicts

Criterion Composites*	Within-Group Comparisons				Between-Group Comparisons
	Long-term (N=228)		Short-term (N=67)		
	Admission	6-mo Follow-up	Admission	6-mo Follow-up	Posttreatment P Values†
Medical composite	9.6	5.1	8.1	6.6	<.05
Medical problems, days	8	3	9	6	. . .
Employment composite	12.4§	−2.7	11.6§	−3.8	<.05
Days worked	3§	10	4§	12	. . .
Money earned, $	565§	341	77§	288	<.05
Alcohol composite	17.0§	11.9	19.4	19.0	<.01
Drinking, days	8‡	5	9	11	<.01
Intoxicated, days	5‡	2	6	6	. . .
Drug composite	27.0§	3.0	28.1‡	14.8	<.01
Opiate use, days	13§	3	11‡	7	<.01
Nonopiate use, days	5§	1	5	5	<.01
Legal composite	20.1§	3.0	22.8	23.2	<.01
Crime, days	10§	1	7	8	<.05
Illegal income, $	309§	23	526§	188	<.05
Family composite	15.1‡	9.4	9.6	9.7	<.05
Family problems, days	11‡	3	8	9	<.05
Psychological composite	14.2§	8.4	13.9§	11.8	<.05
Psychiatric problems, days	11‡	7	12‡	7	. . .

*All criteria were measured during 30 days before admission and before six-month follow-up.
†Covariates were age, race, number of previous treatments, and pretreatment score.
‡$P<.05$ (Student's paired t test).
§$P<.01$ (Student's paired t test).

health. We have no reason to believe that medical treatment was particularly poor for these patients but, rather, it is likely that the physical problems of these patients were underreported at treatment admission (because of the anesthetic effects of drugs and alcohol) and that the majority of the medical problems that were reported by these patients were chronic in nature, with little chance of significant remission.

Is Patient Improvement a Result of Treatment?

We recognized that despite the significant improvements shown in the alcoholic and drug addict samples, there was no clear evidence that the changes were a result of the treatment process. We needed a comparison group as a control for nontreatment factors, such as maturation, spontaneous remission, and regression,[10] that can account for much of the observed improvements. Ideally, this comparison group would be selected from the same population as the treated subjects, with equal exposure to nontreatment factors but less exposure to treatment. We therefore selected all subjects from the treated population who had received a favorable discharge but had less than 15 days of treatment. The subjects for this ST group were not selected randomly but they were assigned to treatment on the same basis (see "Subjects" section) and in the same proportion as the LT subjects. Thus, it is not possible to argue that the ST patients had entered into less-favored treatments or were assigned differently.

These ST patients may have had less motivation, thereby accounting for their shorter time in treatment. However, they completed five to 14 days of rehabilitation therapy at their assigned program and all received favorable discharges, indicating that they left with adequate discharge planning and were not ejected for disciplinary reasons. Finally, there was no evidence to suggest that these patients had a poorer prognosis at the time of admission or at discharge. We cannot rule out completely the possibility of differences in motivation between the two groups; however, our previous work[11] has shown that neither staff or patient ratings of motivation, nor voluntary vs involuntary admission status is related to length of time in treatment, type of discharge, or treatment performance. We do not contend that the ST group is the optimum control group, only that it is a valid and conservative comparison to the LT group, providing a useful estimate of actual treatment effects.

The between-groups (LT vs ST) analyses of covariance included adjustments for differences in age, race, previous treatments, and each admission criterion score, providing the most direct test possible of the extent to which more treatment was associated with better outcome. The results from these analyses showed significantly better posttreatment status in virtually all areas for the LT patients, especially in the areas of employment, drug and alcohol use, legal status, and psychological function. It is important to note that although the ST groups generally showed some positive change, the LT groups showed significantly better outcomes and larger treatment effects in comparison.

After evaluating the six-month outcome of alcohol and drug abuse treatment in seven different areas, using both within-group and between-group comparisons, the findings were consistent across areas, across alcohol and drug samples, and across the six treatment programs studied. Furthermore, these findings were consistent with our previous evaluation research and with the substantial body of data from other large-scale evaluation studies of substance abuse treatment.[6-9] While no single finding is by itself definitive, we conclude, on the basis of the combined results, that the most parsimonious explanation for these findings is that substance abuse treatment is effective in producing significant, pervasive, and sustained positive change in the lives of these patients.

We have not examined the numerous differences among patients and among treatment programs, or how they interact to produce optimum therapeutic matching. Furthermore, we have not discussed the particular factors during the treatment process that appear to be most closely associated with optimum outcome. These are particularly complex theoretical and methodological issues, which we have examined at length in separate reports.[4,11] Unfortunately, this study, like most other evaluations, has focused on male patients. It will therefore be important for future studies to examine these issues among female populations.

It is important to note that we have not used the word "cure" in this evaluation of treatment effectiveness. It is our feeling that discussions of cure rates or of abstinence percentages give artificial simplicity to what is arguably the most complex, heterogeneous, and chronic health problem in the world. Substance abuse cannot be conceptualized as simply the psychophysiological dependence on drugs or alcohol. If this were true, then the goal of treatment would be simple and direct: the detoxification of the dependent patient. In fact, there are now a number of methods available for rapid and safe detoxification from virtually all drugs. However, detoxification by itself is clearly an ineffective treatment, generally resulting in relapse within one month.[2,10,13]

Our past work and our clinical experience indicate that substance abuse occurs in persons who commonly have associated problems in the areas of physical health, employment, legal status, family relations, or psychological function. Regardless of whether these associated problems preceded or resulted from the chemical dependence, they can have a profound effect on the patient's response during treatment and can leave him chronically susceptible to relapse following treatment. It is comparatively easy to eliminate at least the acute signs of a patient's psychophysiological tolerance to alcohol or drugs through detoxification alone. It is much more difficult to sustain that condition through improvements in the constellation of associated problems. Yet, the data presented here and elsewhere suggest that substance abuse treatment can be effective in this larger goal.

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Statement of Mark W. Parrino
President
Northeast Regional Methadone Treatment Coalition
Before The
U.S. House of Representatives
Select Committee on Narcotics Abuse and Control
Efficacy of Methadone Maintenance Treatment
March 23, 1990

I appreciate being invited to testify before this Committee regarding the efficacy of methadone maintenance treatment and its critical public policy issues. I am representing methadone treatment providers in the ten member states of the Northeast Coalition. I have been directly involved in the provision of methadone maintenance treatment since 1974 and have served as the Director of Gramercy Park Medical Group, a methadone program treating 400 patients, since 1980.

Efficacy of Methadone Treatment

A successful methadone treatment system must be flexible in structure and properly funded if it is expected to respond to changing patient characteristics. The infrastructure of this country's methadone treatment programs is fragile. In spite of its success in effectively treating heroin addicts, which has been repeatedly documented in research findings for

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over twenty years, methadone maintenance has barely survived years of inadequate funding and extremely negative public relations. It has always remained on the fringe of mainstream health care. In many respects, it is remarkable what has been achieved, given the available resources and prevalent social attitudes.

At present, the nation's methadone treatment programs are experiencing considerable turbulence as a result of increased HIV Infection among intravenous heroin addicts and increased cocaine/crack abuse.

The existing methadone treatment system must improve if it is expected to treat heroin addiction in conjunction with these new realities. It must offer more comprehensive medical and counseling services on site in responding to the needs of the present patient population. The program managers and staff require enhanced professional training to reshape the treatment environment. The public must be better educated about the value of methadone maintenance under this new set of circumstances. Performance-based standards of care should be developed and implemented to better guide the treatment system toward enhanced outcome. Finally, methadone treatment programs will require greater financial support to meet these objectives, which will be especially difficult in the present era of cost containment by third party payors.

Interim Methadone and the Need to Expand Treatment

The member states of the Northeast Methadone Coalition support the immediate and aggressive expansion of comprehensive methadone treatment services wherever they are needed.

In our opinion, the proposed Interim Maintenance Rule represents a badly conceived public policy. It moves treatment expansion in the wrong direction at a time when more services need to be provided. The Northeast Coalition opposes Interim Maintenance for the following reasons.

Patient Characteristics Have Changed

Most addicts used heroin as their primary drug of abuse at the inception of methadone treatment during the 1960's.

At present, heroin addicts enter methdone treatment with serious multiple addictions, particularly to cocaine/crack and alcohol. A greater number are homeless, uneducated and unemployed. A greater number are seriously ill since patient morbidity has increased with the incidence of HIV infection and AIDS. Patients are at greater risk for tuberculosis, pnemonia and a host of infectious diseases.

Some proponents of the Interim model have indicated that some care is better than nothing at all. This is a specious argument that does not hold up to the findings of current research. The Northeast Coalition has carefully evaluated the research findings of Dr. John Ball and his associates, "Reducing the Risk of AIDS Through Methadone

Maintenance Treatment". The Coalition is submitting a copy of this important study in conjunction with this testimony, so that it will be made part of this hearing's public record. Dr. Ball's conclusions indicate that better quality [comprehensive] methadone programs achieve a greater degree of effectiveness in reducing intravenous drug use, which is a critical objective in decreasing the incidence of HIV infection among such drug abusers. Dr. Ball's research found that : "Marked differences in the effectiveness of various programs were observed: current intravenous use varied from less than ten percent to over fifty-seven percent of patients in particular treatment programs...It is a major finding that some methadone maintenance programs are markedly more effective than others in reducing IV drug use and needle sharing among their patients because these differences in treatment outcome are related to definite program variables. The more effective programs have high patient retention rates, high rates of scheduled attendance, a close, consistent, and enduring relationship between staff and patients, and year-to-year stability of treatment staff...Effective and ineffective programs, however, did not differ with regard to patient characteristics."

The Coalition has not reviewed any independent published data documenting the efficacy of Interim Maintenance regarding retention in treatment, the reduction of intravenous drug abuse, the reduction of other drug and alcohol abuse, and the improvement of the individual's general well being.

The Methadone Coalition firmly believes that it is counter-therapeutic and dangerous to offer fewer services with fewer resources to an even greater number of seriously ill heroin addicts. Many methadone programs are oversubscribed and understaffed. Admitting hundreds or thousands of HIV seropositive heroin addicts into such programs by eliminating basic quality assurance standards would be disastrous for all parties. The methadone treatment system would become dysfunctional under such circumstances.

Patient Loitering and Methadone Diversion

Two issues that have created serious problems for methadone treatment involve patient loitering in the vicinity of the program and the diversion of "take-home" medication by the patient to the illicit market. Patient loitering is a program management-security matter. Increased surveillance of patients in the program area will not resolve the underlying problem of unemployed or dysfunctional individuals but it will eliminate a visable symptom. A methadone program sustains its continued existence by keeping as invisable as possible to the surrounding community. Unfortunately, a small percent of patients are responsible for this problem.

A treatment program can prevent loitering by having well established policies, which are integral to the treatment process, and enforced by a well managed security complement. Security personnel must maintain an understated but active presence outside the methadone program to monitor patient activity within a well defined perimeter. An individual, who is repeatedly observed loitering in the area, should be evaluated for transfer into another methadone program. While this intervention may appear counter-therapeutic for the individual patient, especially if the patient is discharged from care, it preserves the continued existence of the program for more motivated people. No treatment program can be all things to all patients. There are a number of patients, who are not treatable in an outpatient setting. A history of heroin addiction does not necessarily mean that the individual will always benefit from methadone maintenance.

Methadone Diversion

A number of methadone patients sell their medication to untreated drug users, who either do not need or want methadone maintenance or are unable to meet the established admission criteria. Making good quality treatment more readily available could reduce the frequency of this dangerous practice since many buyers of illicit methadone would seek treatment.

The illicit sale of methadone is a serious matter and has done considerable damage to the public's trust in the value of methadone treatment. A non-tolerant individual can die as a result of ingesting an illicit dose of methadone.

In my experience as a program administrator, I know that some of the patients will sell their medication. Most of the patients take their medication as prescribed. Gramercy Park

Medical Group has a policy of discharging patients who are found to be selling their medication. The most unstable patients are compelled to attend the clinic each day while more responsible patients remain on reduced visit schedules. Weekly toxicology results are an integral part of clinical decison-making.

Some people believe that all treatment programs should be open seven days per week and that all patients should attend the clinic each day. Existing research does not support this perspective. Such punitive practices are unnecessary and would be counterproductive. Responsible and successful patients, including people with full-time jobs, homemakers and students, would be driven out of treatment.

Developing Performance-Based Treatment Standards

The standards of methadone treatment programs vary markedly within cities and states as documented by Dr. John Ball and his colleagues in the aforementioned study. There is no nationally recognized standard of quality care. Some states arbitrarily restrict the amount of time that a patient can remain in methadone treatment, which is dangerous to the patient and jeopardizes his sustained recovery from heroin addiction. Other states limit the patient's methadone dosage to a pre-determined ceiling regardless of the individual's medical needs, which runs counter to the practice of responsible medical care. Some treatment programs make a practice of detoxifying pregnant women under the incorrect belief that the child will be better off. In fact, considerable harm can be done to both the mother and fetus. As a result of these practices and policies, patients are treated badly.

The Food and Drug Administration promulgated process review standards in 1974, which have been adopted or made more stringent by single state regulatory authorities. These explicit standards monitor the presence or absence of pre-determined record keeping elements. Process review criteria do not evaluate patient outcomes such as (1) patient retention in treatment; (2) the reduction of narcotic use through the proper methadone dosage; (3) reduction of alcohol and other drug use through counseling intervention; (4) reduced criminal activity, (5) improved physical health through the diagnosis and treatment of chronic illnesses; or (6) improvement in social functioning through vocational education, training and job placement. The Northeast Coalition supports the development of such performance-based criteria.

I appreciate having had this opportunity to present the Northeast Methadone Coalition's views on the selected topics and would be happy to respond to the Committee's questions.

Reducing the Risk of AIDS Through Methadone Maintenance Treatment

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In a three-year field study of methadone maintenance programs in New York City, Philadelphia, and Baltimore, treatment was found to be effective in reducing IV drug use and needle sharing among most heroin addicts. Of 388 patients who remained in treatment for one year or more, 71 percent had ceased IV use. Conversely, 82 percent of patients who left treatment relapsed rapidly to IV drug use.

Marked differences in the effectiveness of various programs were observed: current IV use varied from less than 10 percent to over 57 percent of patients in particular treatment programs. This differential effectiveness was related both to length of patient's stay and to the quality of treatment provided.

HIV seropositivity among high-risk drug users is related to frequency of injections and needle-sharing contacts. Effective methadone treatment can stop these practices, but a widespread impact on the AIDS epidemic will require improvement of treatment in many programs.

In the past few years, drug abuse treatment research has received a new mandate: to find treatment for patients that is not only generally rehabilitative but also specifically effective in reducing intravenous drug use and needle-sharing practices among heroin addicts and others who resort to injections (Clayton 1986; Drotman 1987; Stimmel 1987). This concern about IV use was caused by the AIDS epidemic, although other medical and epidemiological problems associated with IV use have been recognized as well (Ball and Chambers 1970; Lowinson and Ruiz 1981) since this route of administration was first followed in the 1920s in the United States (O'Donnell and Jones 1968). Now, however, AIDS adds a new urgency to the search for effective treatment. Currently IV drug users constitute the second largest population group in the United States at risk for AIDS (Centers for Disease Control 1987; Des Jarlais, Friedman, and Hopkins 1985; Ginzburg, MacDonald, and Glass 1987; Hardy, Allen, Morgan, and Curran 1985). In New York City some 50 percent of heroin addicts are infected with the human immunodeficiency virus (HIV) (Des Jarlais and Friedman 1987a); in Baltimore the rate is 29 percent

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(Lange, Snyder, Lozovsky, Kaistha, Kaczaniuk, and Jaffe 1987). In addition, intravenous drug users are the principal transmitters of HIV to the heterosexual population and to the newborn (Des Jarlais et al., 1985; Pyun, Ochs, Dufford, and Wedgwood 1987).

The search for an effective means of treating and rehabilitating opiate addicts has a long history in the United States. The difficulty of effecting a cure or long-term improvement among chronic addicts has been documented repeatedly. In their classic compendium, *The Opiate Problem*, Terry and Pellens (1928) described how this problem developed and changed during the nineteenth and early twentieth centuries. They traced the rise and fall of various treatment regimens which endeavored to mitigate or cure opiate addiction. Although some success was reported for diverse treatments at various times, the overall finding was that the successful treatment of chronic addiction is extremely difficult and problematic.

The search for effective treatment has continued since the 1920s. Public Health hospitals were established in the 1930s at Lexington, Kentucky and Fort Worth, Texas to treat opiate addicts from throughout the United States (Martin and Isbell 1978). After World War II, community-based treatment programs for heroin addicts were initiated, with the result that therapeutic communities and methadone maintenance therapy became available in many cities (Jaffe 1979). In recent years two lines of treatment research have been emphasized. One approach is to focus on the efficacy of matching particular groups of patients to specific modalities of treatment (McLellan, Luborsky, O'Brien, Woody, and Druley 1982). The other is to evaluate specific programs or clinics on the basis of their effectiveness in treating addict patients with respect to "performance based ratings" (Dole, Nyswander, Des Jarlais, and Joseph 1982). This latter approach measures program effectiveness on the basis of treatment dropouts, positive urines, criminal behavior and other pertinent variables. Both of these approaches are necessary in the evaluation of treatment—determination of patient characteristics and program performance.

In this paper, the principal research issue is to ascertain the effectiveness of methadone maintenance treatment in reducing IV drug use and concomitant needle sharing practices among addict patients. Specifically, four research questions were addressed: 1) To what extent does long-term methadone maintenance treatment reduce IV use and needle sharing?; 2) Are some programs markedly more (or less) effective than others?; 3) To what extent and how rapidly does relapse occur when patients leave treatment?; and 4) Are patient characteristics or program characteristics more important in reducing IV use and needle sharing during treatment?

Although the three-city treatment evaluation project from which this paper was derived was not designed to test psychosocial theories of addictive behavior (Lettieri, Sayers, and Pearson 1980), research findings pertaining to the continuation or cessation of intravenous drug abuse have various theoretical ramifications. Thus if it is found that patients' pretreatment social and drug history characteristics are associated with successful change during treatment and, concomitantly, that there are only minor variations in success rates among the programs studied, this finding would support psychosocial theories that stress the primacy of early etiological factors and long-term socialization in the addict subculture. Conversely, if successful treatment is associated primarily with specific programs and if pretreatment patient characteristics are found to be of lesser importance, these findings would support resocialization theories that stress programmatic and group efforts at interrupting addictive or deviant behavior (DuPont, Goldstein, O'Donnell, and Brown 1979). It may be assumed that both sets of influences (pretreatment and in-treatment) are operative; the research problem is to ascertain the relative influence of each on outcome criteria.

In considering the theoretical implications of the research issues addressed, it is pertinent to note that treatment success as defined here (cessation of IV drug use) refers primarily to patients who remain in methadone maintenance treatment for two or more years. Thus analysis is restricted largely to those patients who remain in continuous treatment in the same program for some years. One also must address the collateral issues of why most patients drop out of treatment and why many addict patients do not seek treatment. Although these two issues remain largely unresolved and (especially in the case of untreated addicts) difficult to investigate, it is feasible and important to determine whether existing treatment programs are effective in reducing or stopping intravenous drug use and needle-sharing practices among their patients.

Methadone Maintenance Treatment

Effective methadone maintenance treatment involves long-term rehabilitation of addict patients. As Vincent Dole observed almost 20 years ago (Dole 1971), this rehabilitation has two principal aspects. First, it is necessary to interrupt the addict's self-destructive lifestyle, which involves daily drug-seeking behavior and intravenous injections; this process entails getting him off illicit street drugs and controlling his physical addiction. Second, it is necessary to provide long-term rehabilitative support and services. These two aspects of rehabilitation (withdrawal from illicit drugs and lifestyle changes) are interrelated; both must be addressed consistently during treatment.

Contemporary methadone maintenance treatment in the United States is a specialized type of rehabilitation for heroin addicts. The principal features of this treatment are as follows:

- A prescribed dose of methadone is dispensed daily at a clinic to each addict patient. Methadone is consumed orally under direct supervision in order to prevent diversion, arrest IV use, and ensure patient compliance in medication, and thereby to provide a substitute for heroin use.
- Patients are provided with long-term rehabilitative support and services. These include a close, consistent relationship with a designated drug abuse counselor, who is seen twice a month in individual sessions and more frequently and informally as needed; medical care and referral services; and some educational and vocational services (usually minimal).
- Treatment is monitored and controlled on a daily and weekly basis. Patients have a set schedule of attendance; they are monitored daily for drug abuse behavior and other problems (e.g., alcohol intoxication) by the dispensing nurses or counselors. Urine specimens are collected weekly at the clinic. As noted, counseling and medical sessions are scheduled.
- Patient care is individualized; treatment regimen is changed as patients improve. Thus, take-home methadone medication is allowed on one day or more per week as patients improve (i.e., cease drug use, adhere to clinic rules, obtain employment). Conversely, clinic privileges can be withdrawn for adverse behavior: drug abuse (i.e., as detected by urinalysis), missed attendance, fighting or loitering, and so forth.
- A separate director or administrator coordinates and supervises the operation of each clinic. He or she may be a physician, a counselor, or an administrator.
- Methadone maintenance programs are relatively small clinics with 200 to 300 patients; usually they are located in separate quarters in old buildings on commercial avenues in center-city or slum neighborhoods.

METHOD

The research findings pertaining to IV drug use were derived from an intensive three-year study of six methadone maintenance programs in three Eastern cities, two each in New York, Philadelphia, and Baltimore. We selected only large, stable programs with average or above-average staff-patient ratios in order to exclude transitory or grossly inadequate programs. The six programs were studied intensively on site over a three-year period by a four-person research team which included a sociologist, a clinical psychologist, a pharmacist, and a drug abuse counselor. Treatment services at each clinic were measured through structured interviews with the entire staff, systematic observation of clinic operations, and comprehensive record reviews (Ball, Corty, Petroski, Bond, Tommasello, and Graff 1986).

The 633 male methadone patients selected for study at these six programs were initially interviewed in winter 1985–86; and 506 of these patients were reinterviewed in winter 1986–87. Twelve professional interviewers completed face-to-face interviews with the addict patients in confidential conditions which facilitated cooperation by patients and resulted in a low refusal rate. The interviews were voluntary, were held in private, and were conducted by extramural staff members; the completed schedules were removed from the clinic when the interviews were finished. Patients were paid $10 or $15 per interview depending upon the program.

The 633 patients included at least 100 from each clinic. Two types of patients were interviewed at each site: new admissions and persons currently in treatment. The new admissions were interviewed during an eight-week period in late 1985 from consecutive admissions at each clinic. The in-treatment patients were a representative sample of each clinic's patient population in treatment at least six months. Of the 633 patients, 113 were new admissions and 520 belonged to the in-treatment sample.

The principal instrument used in the patient interviews was the Addiction Severity Index (ASI) (McLellan, Luborsky, O'Brien, and Woody 1980). This instrument has been employed extensively in drug abuse treatment research, and its reliability and validity have been established (McLellan, Luborsky, Cacciola, Griffith, Evans, Barr, and O'Brien 1985). The ASI measures the following seven areas: medical status, employment or support status, alcohol use, drug use, legal status (i.e., crime), family and social relationships, and psychiatric status. In addition to administering the ASI, we asked questions on drug abuse history, treatment experiences, and criminal behavior.

The findings pertaining to current IV use and needle-sharing practices were obtained from the second interview with 506 patients. The second interviews were conducted at the clinics, or in the community if the patients had left treatment. We obtained 399 interviews with patients in treatment and 107 interviews with patients who had left treatment. Of the in-treatment sample, seven patients reported no history of intravenous drug use, three interviews were classified as invalid on the basis of standard ASI criteria (i.e., three or more invalid scales) and one patient did not provide answers about his history of intravenous drug use. With these 11 cases removed, the in-treatment sample consisted of 388 patients. The out-of-treatment sample is discussed separately below.

In the second face-to-face interview, questions were asked about the type and frequency of injections during the addict's last period of IV drug use; this period was defined as the month preceding the last injection of illicit drugs. We obtained information on the number of days per month of both IV use and needle sharing. We measured days per month of IV use for two reasons: 1) this procedure was used in prior research (Nurco, Cisin, and Balter 1981) which indicated that recall was facilitated by the days-per-month schema, and 2) this procedure reduced the distortion introduced by extremely high values, such as persons who injected 200 or more times a month. Other researchers have used the number of injections per month as a measure, which also has advantages (Marmor, Des Jarlais, and Cohen 1987). The two procedures are supplementary in that each provides particular data sets.

Of the 506 male addicts interviewed in 1986–87, 399 were still in the same treatment programs as in 1985 and 107 had left methadone maintenance treatment. These two samples are first analyzed separately and then compared with respect to current IV use and needle-sharing practices.

The present paper focused on IV use rather than on needle-sharing behavior because needle-sharing frequency responses obtained from addicts tend to underestimate the extent of this practice. This occurs because addicts tend to define needle sharing in a restricted sense; for example, they include needle sharing only for profit or with strangers. Beyond this point it is worth noting that intravenous drug use is fundamentally a group activity. Heroin addicts commonly receive their first shot—their "wings"—from another addict and continue to participate in the social relationships, including sharing drugs, needles, and works, that accompany the life of heroin addiction (Novick, Klan, and Kreek 1986). Thus needle sharing can be viewed as a corollary of intravenous drug use (Des Jarlais, Friedman, and Strug 1986). It remains to be determined to what extent this close association between IV use and needle sharing can be altered in the AIDS era through specialized treatment, education, and other prevention efforts (Des Jarlais et al. 1987b; Friedman, Des Jarlais, Sotheran, Garber, Cohen, and Smith 1987).

Although considerable literature exists pertaining to the effectiveness of methadone maintenance treatment (Cooper, Altman, Brown, and Czechowicz 1983; Tims and Ludford 1984), these studies do not refer to the reduction of intravenous drug use as an outcome variable. To rectify this situation we planned several treatment studies which will measure the prevalence of IV drug use, needle sharing, and HIV seropositivity among drug abuse patients.

RESEARCH FINDINGS

Last Period of Intravenous Drug Use For Patients in Treatment

When we asked the 388 patients the month and year of last intravenous drug use, 18.6 percent gave a date that preceded their current treatment, 17.8 percent gave a date that coincided with their admission, 21.9 percent gave a date that occurred after they had entered treatment, and the remaining 41.8 percent reported IV use in the past year. This last group included those who reported IV use in the past year but not in the past month (12.9%) as well as those who reported IV use in the past month (28.9%).

Figure 1 shows the overall findings with regard to the effectiveness of methadone maintenance treatment in reducing intravenous drug use. All of the addicts under study were prior IV drug users; hence this 100 percent prevalence represents the last addiction period that preceded their current treatment. Prevalence of IV use at admission was 81 percent, as some addicts were incarcerated or in other treatment before their current admission. During their admission period, IV use prevalence dropped from 81 to 63 percent. This rapid decline continued during long-term treatment, but at a lesser rate. After four years of outpatient methadone maintenance the prevalence of IV use was reduced to 29 percent. In sum, then, IV drug use was reduced by 71 percent from prior addiction status.

Thus these patients showed considerable variation as to when and under what circumstances they stopped their intravenous drug use, or whether they had given it up at all. All of the intreatment sample had been in treatment for at least a year; most had been in treatment for two or more years. At the time of the second interview in 1986 the mean time in treatment was almost four years (Table 1).

Many of the 72 patients who had ceased IV drug use before their current treatment entered from jail or other treatment programs (Group A, Table 1). It is significant that these patients did not relapse to IV use *at all* during the 53 mean months of their current treatment because their prior frequency of IV use was high: 21 days per month. This group can be classified as treatment successes with respect

FIGURE 1. Effect of Methadone Maintenance Treatment on IV Use for 388 Male Methadone Patients in Six Programs

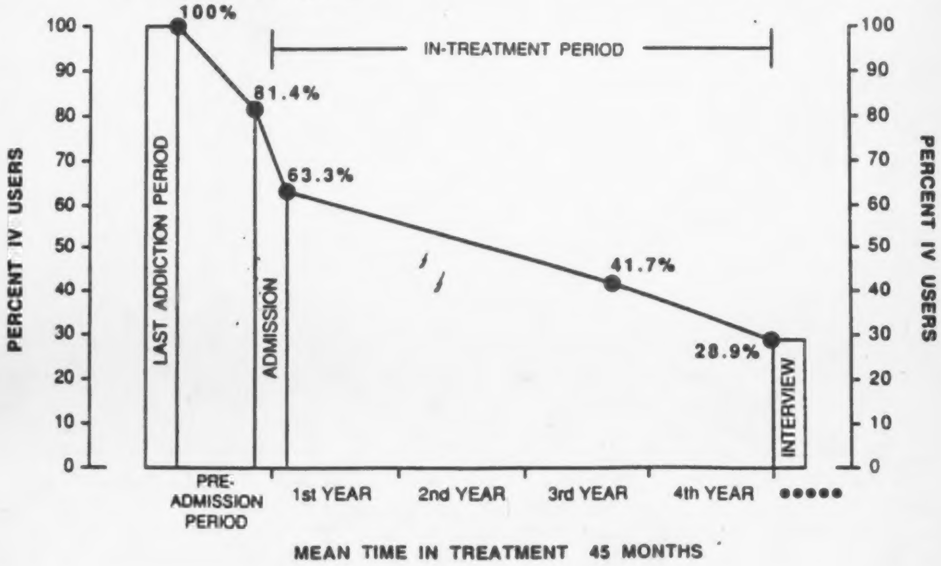


TABLE 1. Frequency of Intravenous Drug Use and Needle Sharing during Patients' Last IV Use Period[a] for 388 Male Patients in Methadone Maintenance Treatment

Treatment Status at Last IV Use	(1) Patients in Each Status		(2) For Each Group. Mean Months in Treatment	(3) IV Use. Mean Days Per Month	(4) Needle[b] Sharers in Last Period		(5) Frequency Needle Sharing Days per Month (per Positives)
	N	%			N	%	
A. Before current treatment	72	18.6	52.5	20.9	31	47.0	11.1
B. At admission (two-month period)	69	17.8	35.5	25.2	33	49.3	15.1
C. During treatment	85	21.9	66.2	10.1	20	34.5	8.2
D. Last year (11 months)	50	12.9	33.8	8.5	5	13.9	4.4
E. Current IV use—last month	112	28.9	35.0	11.2	29	29.9	7.5
Total	388	100.0	45.0	14.9	118	36.4	10.6

[a] Last IV use period is the month preceding each patient's last injection of illicit drugs.

[b] Needle sharing during most recent period of IV drug use. Needle-sharing frequency data were available for 324 subjects; Column 4 calculations are based on these patients.

to discontinuation of IV use and concomitant needle sharing.

Almost one-fifth of the patients (Group B, Table 1) gave up their IV use at the time of admission (i.e., a month before or after admission). This finding establishes that methadone maintenance treatment can stop IV use rapidly among some heroin addicts. This cessation of IV drug use persisted over the entire 36-month period in which these patients underwent treatment. As with the previously described group, the frequency of prior IV use was high: 25 days per month. Consequently this group of addict patients also can be classified as treatment successes.

Another one-fifth of the patients ceased IV drug use after admission to treatment (Group C, Table 1). Cessation of IV use for this group was gradual over the years. With regard to last frequency of IV use, these patients had markedly lower use rates (10 days per month) than the preadmission or admission groups; this lower frequency of IV use may reflect the partial effect of treatment. Because these patients ceased IV use while in treatment, they too can be considered as successes.

Patients who reported IV drug use during the past year but not in the past month (13%; Group D, Table 1) appear to be a transition group, some of whom are in the process of cessation. This interpretation is supported by the lower frequency of IV use (8.5 days). At the same time, most of these patients have yet to achieve long-term discontinuation. Therefore this group can be considered only as transitory or partly successful.

Of the 388 patients in treatment, 112 reported IV use during the past month. The mean frequency of IV use per month was 11.2 days; some reported continuous use to the day of interview. This group of current IV users is classified as treatment failures.

The Extent of Needle Sharing among the Five Patient Groups

Of the 324 male patients for whom relevant data were available, 118 reported that they had shared needles during their last period of IV use. Although the percentage of patients who shared needles was higher before treatment (Table 1, Groups A and B) than after methadone maintenance treatment was begun (Groups C, D, and E), this difference was not statistically significant.

The effect of treatment on needle sharing is evident. Thus, the frequency of needle-sharing days was significantly lower for sharers whose last IV use occurred after admission (Groups C, D, and E) than for the admission or preadmission groups (A and B); $t = 4.689$, df 177.1 using separate group variances, $p < .001$.

To recapitulate, 36.4 percent ($N = 118$) of 324 patients had shared needles during their last or current period of IV use. Of these needle sharers, 64 had stopped this practice before or during admission, 20 stopped during treatment, five had stopped at least temporarily (for the past month) and the remaining 29 still continued to share needles. This last group—active needle sharers—constituted nine percent of the patients in treatment.

RESULTS

Program Differences in Effectiveness

From the overall findings pertaining to IV use, it might be concluded that methadone maintenance treatment is quite successful for some 60 percent of patients who ceased IV use for at least one year, but has only limited success or is a failure for the remainder. Such a conclusion assumes relative uniformity in effectiveness among programs; but this assumption was found to be incorrect.

We had anticipated that the six programs selected for study would contain some variation in program characteristics and treatment services provided to patients, even though the original selection procedure was designed to exclude inadequate programs. We had not anticipated, however, that we would find such marked and such persistent differences. After our first comprehensive on-site evaluation of each program, we found wide variations in the type, frequency, and quality of treatment provided to patients (Ball et al. 1986). Given these findings, we investigated whether these differences affected IV drug use among patients in treatment.

The six methadone maintenance programs varied greatly in effectiveness of reducing IV drug use among patients in treatment (see Table 2). The most striking finding is the range in the percent of patients who were current IV drug users—from 9.8 percent to 57.1 percent. Four of the programs were reasonably effective; IV use stopped among 75 to 90 percent of their patients. In two programs, however, over 56 percent of the patients are still injecting drugs.

Marked differences also exist with respect to other indicators of program effectiveness. In one program 38 percent of the patients stopped IV use at admission, while in two others only four to eight percent did so. Significantly, there was a high positive association between success at admission and success in keeping patients from current IV use (Spearman rank correlation .9429, $p < .05$). Again, it is revealing that four of the programs affect IV use at admission for a sizable portion of their patients (14 to 38%) while two affect less than eight percent.

These considerable differences in effectiveness were unexpected. Although we had anticipated that there would be minor variation in outcome due to program differences, we thought that the dominant influence upon treatment success would be patients' characteristics, such as length of addiction, employment history, prior criminality, and severity of psychiatric symptoms. This expectation was not substantiated by the research findings; instead we found program treatment variables to be of paramount importance in reducing IV usage. This topic is investigated more systematically in the discussion of multivariate analysis.

TABLE 2. Differential Effects of Treatment Programs: Last IV Drug Use by 388 Male Patients in Six Methadone Maintenance Programs

		Last Period of IV Use					
		Percent reporting last use in each period					
Treatment Program	Sample N	(1) Before Treatment	(2) At Current Admission	(3) While in Treatment	(4) During Past Year[a]	(5) Current Month	*Not* Current IV Users %
A	82	18.3	37.8	28.0	6.1	9.8	90.2
B	62	30.6	17.7	21.0	12.9	17.7	82.3
C	65	27.7	13.8	24.6	15.4	18.5	81.5
D	64	18.8	17.2	23.4	15.6	25.0	75.0
E	66	10.6	7.6	12.1	13.6	56.1	43.9
F	49	2.0	4.1	20.4	16.3	57.1	42.9
Percent	100.0	18.6	17.8	21.9	12.9	28.9	71.1

[a] Column 4 refers to IV use in past year, but does not include past month (Column 5).

The Dropout Sample

One-third of the patients had dropped out of treatment in the six programs during the year following their first interview. Of these patients, 107 (48%) were reinterviewed in the community. When we compared dropouts who were reinterviewed with those who were not reinterviewed, we found no significant differences in demographic or addiction characteristics.

Two of the 107 interviews with treatment dropouts were judged to be invalid on the basis of ASI criteria. The remaining dropout sample consisted of 105 male ex-patients who had left methadone maintenance treatment during the prior year.

The overall finding is that 71 of the 105 dropouts relapsed to IV use after leaving treatment (see Table 3); their mean time out of treatment was 7.2 months. The relationship of time out of treatment to relapse is linear and highly positive (Figure 2). We obtained an estimate of the annual relapse rate from those addicts who had been out of treatment for 10 to 12 months; this rate is 82 percent.

Of the 105 dropouts from treatment, 19 shared needles. The percentage of needle sharers tended to increase with time out of treatment; 48 percent of those out of treatment for 10 to 12 months reported this practice.

FURTHER ANALYSIS: COMPARISON OF SAMPLES

In order to compare dropouts with patients who remained in treatment, we analyzed the two groups with respect to relevant pretreatment characteristics. We found that the dropouts had spent less time in their prior methadone maintenance treatment (24 versus 45 months), were less likely to have been employed (29 versus 53%) and were somewhat younger than those still in treatment (36 versus 38 years). The two groups did not differ significantly, however, with respect to age at onset of opiate use, length of heroin addiction, number of prior treatments, race, years of schooling, or years in prison (see Table 4).

The life history findings pertaining to the 493 addicts included in this comparison substantiate both the scope and the chronicity of behavior problems that accompany heroin addiction (Table 4). On the average these patients have been in prison for more than two years; they began their addiction as teenagers; they have sustained their heroin addiction for 11 years; their work history is marginal; they were in prior treatment for their drug use three times. The chronicity of their addiction continues as they approach 40 years of age. How to alter this lifestyle and cope with its consequences remains as a special challenge to those involved in studying the AIDS epidemic (Kaplan, Johnson, Bailey, and Simon 1987; Galea, Lewis, and Baker 1988).

DISCRIMINANT FUNCTION ANALYSIS: PROGRAM VERSUS PATIENT CHARACTERISTICS

As both program variables and patient characteristics were found to be associated with cessation of IV use, we undertook analysis to determine the relative effects of these two factors in reducing or stopping IV use by addicts who enter methadone maintenance treatment.

We conducted discriminant function analysis of individual and program variables to

TABLE 3. Intravenous Drug Use and Needle-Sharing Frequency of 105 Treatment Dropouts, by Months Since Leaving Treatment

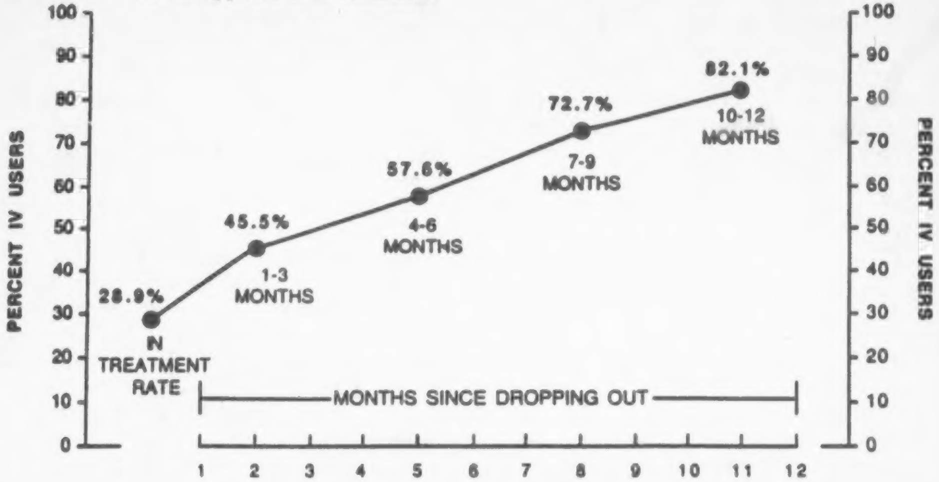
			IV Use Since Drop-Out		Needle Sharers		
Months since Treatment[a]	N	Months in Last Treatment	Yes—%	Per Month,[b] Mean Days	N	%	NS—Days Per Month[c]
1–3	11	45.2	45.5	16.8	2	40.0	14.0
4–6	33	24.4	57.6	15.6	3	15.8	4.3
7–9	33	19.0	72.7	10.4	3	12.5	9.7
10–12+	28	21.1	82.1	17.0	11	47.8	12.4
Total	105	24.0	67.6	14.5	19	26.8	10.8

[a] Mean months since leaving treatment = 7.2 months for the 105 former patients.

[b] For those who relapsed to IV use.

[c] Number of needle-sharing days per month during last monthly period of IV use.

FIGURE 2. Relapse to IV Use After Methadone Maintenance Treatment for 105 Male Addicts Who Dropped Out of Treatment



ascertain which of these were associated most closely with the cessation of IV drug use. The dependent variable in the analysis is IV use, with the groups defined as indicated in Table 1. The independent (or predictor) variables are age at interview, years of heroin use, number of years of cocaine use, number of prior treatments, number of months incarcerated, number of months in current treatment program, race, program membership, and methadone dose level. Three discriminant functions were significant at the .05 level. Because the first two functions accounted for 83.95 percent of the variance, analysis was confined to these two.

The first function discriminates between current IV users (Groups D and E) and those that have ceased IV use (Groups A, B, and C). This function, then, is a determinant of current IV use. The second function differentiates between Groups A and B—between those patients who stopped IV use before treatment (e.g., in jail) and those who stopped at admission to treatment. The second function, then, identifies success during the admission period.

Three factors were found to be correlated highly with the first function: methadone dose level (−.70), membership in Program F (+.54), and membership in Program E

TABLE 4. Pretreatment Characteristics of 493 Male Methadone Maintenance Patients, for Intreatment and Dropout Samples

Patient's Characteristics	Total Patients (N=493)	In-Treatment Sample (N=388)	Dropout Sample (N=105)	IT-OT Difference	
				P=	Test
1. Age at onset of opiate addiction, mean years	18.9	18.7	19.7	NS	$t = -1.123$(118.4 d.f.)
2. Years of heroin addication, mean years	11.2	11.4	10.3	NS	$t = 1.188$(191.2 d.f.)
3. Prior treatments for drug abuse, mean number	3.5	3.2	4.3	NS	$t = -1.47$(108.8 d.f.)
4. Months in current (or past) treatment, mean	40.5	45.0	24.0	<.05	$t = 10.43$(311.7 d.f.)
5. Race, percent white	39.6	41.5	32.4	NS	$\chi^2 = 3.148$(1 d.f.)
6. Schooling, mean years	11.6	11.6	11.9	NS	$t = 1.49$(202.1 d.f.)
7. Pre-admission employment, percent full-time prior 3 years	40.5	53.3	29.4	<.05	$\chi^2 = 4.824$(1 d.f.)
8. Years in prison, mean	2.5	2.3	3.1	NS	$t = -1.57$(140.5 d.f.)
9. Age at second interview, mean years	37.7	38.3	35.6	<.05	$t = 3.912$ (199.4 d.f.)

(+.41). Thus as methadone dose level decreased, patients were more likely to be current IV users; patients in Programs F and E were more likely to be current IV users. The important finding is that program and treatment variables (i.e., particular programs and adequate methadone dosage) are related to success; patient characteristics are less significant. This function accounts for 63.9 percent of the variance in current IV use.

Further analysis revealed that a second function differentiates between Groups A & B—between those patients who stopped IV use before treatment (e.g., in prison) and those who stopped at admission to treatment. The second function, then, identifies success at admission to methadone maintenance treatment. The second function is correlated most closely with four factors: enrollment in Program A (+.71), more prior treatment (+.29), more years of heroin use (+.20), and more time in prison (+.17). This function explains 20 percent of the variance (see Table 2).

Although the discriminant function analysis confirms the prior finding of the effects of programs in reducing IV use among patients, investigation of additional program variables and treatment models is indicated; it is necessary to ascertain which program models and which specific types of treatment services account for treatment effectiveness.

DISCUSSION

Several observations about the 71 percent reduction of IV drug use during methadone maintenance treatment are pertinent. It is disturbing that 29 percent of patients report IV use in the past month. Yet for many, IV use was continued at a reduced frequency from pretreatment levels, so that IV use was reduced but did not cease completely. The difficulty of stopping drug use completely among long-term heroin addicts has been a consistent problem since this drug was introduced in the early twentieth century. Indeed, it has been said that no treatment programs exist which will take most opiate addicts off opiates (Ball 1972). Still it is important to note that cessation of IV use occurs for most of the outpatients who remain in regular treatment, because this fact establishes that this goal of treatment can be achieved. At the same time, however, we do not ignore or deny the reality that most heroin addicts do not remain voluntarily in methadone maintenance or in any other treatment modality for as long as two years.

It is a major finding that some methadone maintenance programs are markedly more effective than others in reducing IV drug use and needle sharing among their patients because these differences in treatment outcome are related to definite program variables. The more effective programs have high patient retention rates (especially long-term retention rates), high rates of scheduled attendance, a close, consistent, and enduring relationship between staff and patients, and year-to-year stability of treatment staff. Conversely, the less effective programs are characterized by poor patient attendance, inadequate methadone medication, and high rates of staff turnover. Effective and ineffective programs, however, did not differ with regard to patient characteristics. Indeed, a separate analysis of patients in the six programs revealed an overall similarity in pretreatment characteristics (Corty and Ball 1987).

In considering the marked differences among methadone maintenance programs, it is important to recognize that many treatment programs have inadequate funds, facilities, and staff. In addition, many programs are beset by lack of governmental support and by neighborhood opposition (Friedman and Des Jarlais 1988). The effectiveness of many programs could be increased considerably if these inadequacies and impediments were removed. Certainly it seems reasonable to conclude that many more programs in the United States could achieve the degree of treatment effectiveness in reducing IV drug use which was found among the better programs evaluated in this study.

In considering whether or not these findings from three Eastern cities are typical of the United States generally, several observations are relevant. Both the prevalence of heroin addiction and methadone maintenance treatment are concentrated highly in the Northeast; consequently this region provides the most suitable benchmark for addressing this problem. Second, the results of the present study show a wide range of effectiveness among programs. On the basis of available evidence, it seems likely that comparable variations exist in other regions.

In considering the more theoretical issue of *how* methadone maintenance effects a reduction of IV drug use by patients (as well as concomitant rehabilitation), three major aspects of this treatment deserve comment. First, this modality of treatment is designed to affect heroin addiction directly. Thus a pharmacological intervention immediately provides a substitute for illicit opiates. In this regard, daily administration of oral methadone at a clinic is important because this procedure tends to interrupt and prevent the recurrence of intravenous heroin use.

Second, by providing consistent long-term counseling and other support services, the staff at methadone maintenance programs works to rehabilitate or resocialize addict patients. This interpersonal task transcends pharmacological control of the addiction status; it involves fundamental behavioral changes on the part of the patient. These psychosocial changes in lifestyle commonly require years of continuous intervention rather than weeks or months. Thus the long-term aspect of treatment is crucial if rehabilitation is to occur.

Third, the social control aspect of successful methadone maintenance treatment is important. Not only are pharmacologic and rehabilitative services provided consistently; they are provided under close supervision within a therapeutic environment. A firm yet supportive treatment policy is indicated. This approach commonly requires a consistent concern about and response to missed attendance, illicit drug use, and violation of basic clinic rules (e.g., no fighting or drug dealing). In addition, an effective therapeutic intervention includes consistent concern about each patient's progress with regard to his current work, family, health, and other problems.

Although both the short-term pharmacological and the long-term rehabilitative aspects of methadone maintenance are significant in successful treatment, the latter seem more important with respect to reducing IV use. Thus pharmacologic intervention is seen as a necessary but not a sufficient condition for successful methadone maintenance treatment. The sufficient aspect is long-term rehabilitation.

CONCLUSION

In evaluating the treatment effectiveness of six large methadone maintenance programs in three Eastern cities, we found that this modality of treatment is effective in reducing intravenous drug use by heroin addicts. Thus 71 percent of an in-treatment sample of 388 patients had stopped IV drug use; most had refrained completely from IV use for one year or more.

Marked variation in treatment effectiveness was found among the methadone maintenance programs with respect to the reduction of IV drug use and needle sharing. Thus current IV use varied among programs from less than 10 percent to over 57 percent of the patients in treatment. These findings show that it is possible to operate drug abuse treatment programs at high levels of effectiveness.

In view of the current scope of the AIDS epidemic and the lack of a cure, this disease can be controlled only by preventing further transmission of the human immunodeficiency virus. In this endeavor it seems prudent to support whatever means of prevention is efficacious; methadone maintenance treatment has been found to be an effective means of reducing IV use and needle sharing among heroin addicts who are at risk for AIDS.

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TESTIMONY BEFORE THE SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL

New York, New York
March 23, 1990

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INTRODUCTION

It is a great privilege to appear once again before the distinguished Select Committee on Narcotics Abuse and Control. I last testified before you six years ago. Regrettably, in the intervening years our nation has made no progress in addressing the plague of drug addiction and its associated horrors; indeed, the situation has worsened to an extent even the most pessimistic observer could not have predicted. We have experienced the emergence of crack, the tragic explosion of AIDS cases associated with intravenous drug use, devastating numbers of babies born addicted and/or infected by the AIDS virus, huge increases in our prison population and worsening of the problem of homelessness. We have failed to expand treatment, and thus remain unable to offer prompt help to those who desperately seek life-saving treatment for their addiction. What a sad commentary on our national resolve to address problems associated with such monumental costs in suffering and in dollars, costs which are borne by every single American!

But your knowledgeable Committee does not need me to describe the challenge which is before us, and which we have to date been so ineffective in meeting. Accordingly, I shall limit my testimony to the specific issues raised in the invitation of Chairman Rangel to participate in this Hearing today.

EFFICACY OF METHADONE MAINTENANCE TREATMENT

As the person responsible for the largest methadone program in the country, it would be understandable if my objectivity in assessing efficacy were challenged. Thus, I will cite to you observations of others, who are both knowledgeable and less directly involved in the delivery of this treatment modality.

1. **The National Institute on Drug Abuse**, in an exhaustive analysis in 1983 of the "state of the art of treatment of narcotic addiction," concluded: "To argue that methadone maintenance is not at least as effective as other available modalities for treating this [heroin addicted] population is to ignore the results of the best designed research studies and the consensus of a varied group of experts in the drug/mental health field."[1]

2. **President George Bush** submitted to the Congress of the United States in 1989 his National Drug Control Strategy, which his transmittal letter described as ". . . a thorough, intensive, and unflinching review of Federal anti-drug efforts to date." The Report includes the following statement regarding methadone treatment: "To be sure, methadone treatment is extremely useful. It enables the addict to end his physical dependency on an illegal and incapacitating narcotic, to reduce attendant criminal

activity, and to resume a relatively normal life - working, or attending school."[2]

3. **Dr. James R. Cooper, of the Office of Medical and International Affairs of the National Institute on Drug Abuse**, in an article which appeared in 1989 in the Journal of the American Medical Association, stated: "Evaluation studies that involve large numbers of narcotic maintenance programs have consistently shown this [methadone maintenance] treatment to be highly effective in reducing intravenous drug use and crime and in enhancing social productivity. . . . [E]xpanding methadone programs of quality will significantly improve the current public health AIDS effort. . . . Methadone treatment is clearly the most promising available treatment [of heroin addiction]."[3]

3. **The General Accounting Office of the United States Government**, last summer, presented the findings of a study of methadone treatment. The study was carried out at the request of this Select Committee, and according to the GAO was ". . . prompted by your concern about whether methadone maintenance treatment reduces heroin and other opiate use among those treated, what services are provided during treatment, and how these programs deal with heroin addicts who are also using or addicted to other drugs." With regard to methadone's effectiveness, the GAO answered the questions unequivocally.[4]

The GAO found a wide disparity in results among programs in different parts of the country - a disparity which may be explained by dosage variations which will be discussed below. But with reference to the four programs in New York, GAO reported as follows: "The clinics we visited in New York State had the lowest heroin use for patients in treatment more than 6 months, ranging from 2 to 5 percent." What an astounding demonstration of effectiveness! Within just six months, between 95 and 98% of former hard-core, long-term addicts, who had been self-injecting heroin from three to five times a day - every day - had, according to the GAO, given up heroin use!

With regard to cocaine use, against which methadone has no pharmacological action, the findings inevitably were less dramatic. They were, however, impressive nonetheless. We know that cocaine use among heroin addicts applying for methadone treatment is nearly universal - at least in New York City. And yet, within just six months, between 60 and 90% - according to the GAO - were not using cocaine. Clearly, we continue to have a major, exceedingly difficult challenge in responding effectively to this aspect of our patients' drug problems; equally clearly, however, we are making excellent progress.

I could go on almost endlessly, citing expert studies which have appeared over the past quarter-century in this country and in countries throughout the world. But I believe the conclusion is clear: yes indeed, methadone maintenance is an extremely effective treatment of narcotic addiction.

WHAT MORE SHOULD REGULATORY AGENCIES DO?

A recent study by Dr. John Ball and his colleagues[5] has demonstrated what intuitively was well known: methadone programs, even those located in the same city and serving an essentially identical patient population, vary significantly in their outcomes. Dr. Ball speculated that the number and the attributes of staff members may be key variables, and this speculation is perhaps correct, although data he presented do not seem to justify such a conclusion. What he did observe, however, was a striking correlation between dosage of methadone and the likelihood of persistent heroin use. Apparently many programs are prescribing inadequate doses of methadone.

Dr. Charles R. Schuster, Director of the National Institute on Drug Abuse, referred recently to the "consensus" that ". . . while methadone dosages should be individualized empirically, the most effective dose for the majority of patients is between 50 and 100 mg."[6] And yet, even ten years ago, in a review of nearly 50,000 patients, it was found that some 75% were receiving doses of methadone lower than that ". . . found to be the lowest effective dose."[6] Although more recent data on a national level have not, to my knowledge, been reported, I am convinced that the proportion of patients receiving inadequate methadone dosage has increased further. As Dr. Schuster has noted: ". . . in this age of AIDS, a low-dose policy is not simply inappropriate - it can be fatal to the IV drug abuser in treatment as well as his or her sexual partners and children."

This is a problem. It is causing needless deaths. It is based either on lack of knowledge or, in Dr. Schuster's words, the fact that ". . . the anti-methadone attitude . . . [and the] view that methadone is 'only substituting one addiction for another' logically leads to using lower doses . . . " This Committee can address the problem. It can affirm the efficacy of methadone treatment, on the basis of the world-wide scientific literature that exists, and demand that the Food and Drug Administration and other regulatory agencies promptly undertake a review of prescribing practices of methadone programs throughout the country.

METHADONE DIVERSION

Diversion of methadone is a problem. It is a problem which I believe is far greater for treatment programs and for the vast majority of patients who do not sell their medication than it is for the society at large. On a quantitative basis, it obviously cannot compare to heroin, or cocaine, or marijuana, which enter this country and are sold on street corners of cities throughout the United States in amounts that are measured in tons and not in milligrams. But still, it is a problem.

Illicit traffic of methadone will continue as long as there is a demand for this medication by heroin addicts who - just like the experts quoted above - recognize that it can spell the difference between life and death, but who can not obtain it legally. As was true of the penicillin black market after World War II, the problem can only be addressed effectively by ensuring prompt access to methadone treatment for those who want it and need it.

Your letter of invitation, however, also focused on the specific findings of a recent "spot check" by the New York State Division of Substance Abuse Services of a Beth Israel Medical Center facility located at 103 East 125th Street. I would like to point out that the New York Post article (to which you also refer) concerning this "spot check" bore little relation to the actual "deficiencies" found. Attached to this testimony is the actual "notice" which Beth Israel received, in which the inspectors report: "Observed excessive loitering; people holding and shaking exposed methadone bottles; verbal transactions overheard." For the sake of completeness, I should acknowledge that the inspectors found one (but only one) other deficiency: four charts revealed that "urine results not received from laboratory for long period of time." (Attachment I)

Again, I do not intend to trivialize the State inspectors' findings. They are cause for concern. But they must be viewed in perspective. First, it should be noted that thousands of methadone patients - by definition, all former criminal heroin addicts - are being treated by a variety of programs within a radius of ten blocks of the facility cited. One must also consider the issue of methadone diversion against the reality of at least a million illicit transactions in heroin, in cocaine and in a host of other drugs each and every day in this great City of New York. This is the context in which one must view a recently reported Drug Enforcement Agency "month-long" investigation in the five boroughs of New York, in the course of which 100 containers of illegally diverted methadone were purchased - a total of eight grams.[7]

But my responsibility is not to set law enforcement priorities. I am not trying to get off the hook. I have accepted methadone diversion as a problem, and one that the program for which I am responsible must address. To underscore that Beth Israel Medical Center does indeed take the issue of diversion, and also the problem of loitering, very seriously, I append our response to the Division of Substance Abuse Services inspection cited by you. (Attachment II) Let me assure you that the actions referred to in our response are not platitudes; they are undertaken seriously, and with commitment.

"INTERIM TREATMENT"

A very specific area of concern referred to in your invitation was the role, if any, which "interim" methadone treatment can and should play in our response to the problem of addiction. As you know, extensive testimony was presented to a special panel in Washington, D.C., just last month on this very important issue, and I will take the liberty of citing the brief comments I made at that time:

1. There is one over-riding issue: If not interim treatment, then what? By definition, the only alternative for those who cannot be accommodated by treatment programs is return to the streets for weeks or months until a "slot" is available. Everyone knows what the thwarted applicants do while awaiting enrollment: they shoot dope, three or four or more times each day, thus continuing the highest-risk behavior associated with the spread of AIDS. As you consider the arguments against interim treatment, you must consider this, the only alternative, and decide which makes more sense for the individual and for the general society.

2. Fear has been expressed over the possible impact of interim methadone treatment on "comprehensive" programs. Concern that the introduction of a new form of treatment might adversely affect existing programs is not new. Wherever comprehensive

methadone treatment has been introduced, there has been fear that it would limit the ability of drug-free programs to attract patients, and that their relatively more expensive services would no longer receive government support. In fact, nowhere in the world has this happened, and there is absolutely no basis for concluding that such a fate would befall comprehensive methadone programs should interim treatment be permitted. As you know, interim treatment would only be permitted for those patients who could not be accommodated by comprehensive programs.

3. It has been suggested that interim treatment should be forbidden because it is not necessary. Waiting lists have been viewed by some as a fabrication. In New York, it has been claimed that perhaps a thousand or more slots are vacant in methadone programs today. Even if true, what does this number represent? It represents a 99% utilization of existing treatment capacity. Not bad! What is bad is that these 1,000 slots could accommodate no more than one-half of one percent of the estimated 200,000 intravenous heroin users in the City of New York. That is the problem which interim treatment seeks to address.

CONCLUSION

Congressman Rangel, although we have frequently been portrayed in the news media as having opposing views on matters relating to addiction treatment, I respectfully suggest that there is far more commonality than dissension between us. The bottom line is that we share a deep commitment to those who suffer as a result of the catastrophic drug problem which plagues our nation - that is to say, to every single American, since each and every one of us is a victim of addiction in one way or another. For my part, I applaud your concern and dedication, and your willingness to convene hearings to consider all points of view.

Thank you for your kind attention.

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2. National Drug Control Strategy, U.S. Govt. Printing Office; Washington, D.C., Sept., 1989, Introduction, and page 37.

3. Cooper JR: Methadone Treatment and Acquired Immunodeficiency Syndrome. Journal of the American Medical Association, 262(12):1664-1668.

4. Shikles JL: "Preliminary Funding: A Survey of Methadone Maintenance Porgrams," Testimony of the United States General Accounting Office before the House Select Committee on Narcotics Abuse and Control, Aug. 2, 1989, s. 4.

5. Ball JG, Lange WR et al: Reducing the Risk of AIDS through Methadone Maintenance Treatment. Journal of Health and Social Behavior, 29:214-226, 1988.

6. Schuster CR: Methadone Maintenance - An Adequate Dose is Vital in Checking the Spread of AIDS. NIDA Notes, Spring/Summer, 1989, p. 3.

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ATTACH. I

NEW YORK STATE DIVISION OF SUBSTANCE ABUSE SERVICES

NOTICE OF DEFICIENCY

Program BETH. ISRAEL PRU # 927; 4TH FL

Location 103 E 125 ST Date of Inspection: 2/9/90

REGULATORY CITATION AND DESCRIPTION OF DEFICIENCIES

I. CASE RECORDS (14 NYCRR 1040.17; 1040.5, 1040.6, 1040.9, 1040.11, 1040.12)

15775
119535
59758
45179

URINE RESULTS NOT RECEIVED FROM LABORATORY FOR LONG PERIOD OF TIME.

II. MEDICATION ADMINISTRATION (14 NYCRR 1040.10, Mental Hygiene Law 23.01(a)4)

—

III. MEDICATION SECURITY (14 NYCRR 1040.16, Mental Hygiene Law 23.01(a)4)

—

IV. COMMUNITY PRESENCE: LOITERING (14 NYCRR 1040.19, 1040.21)

OBSERVED EXCESSIVE LOITERING; PEOPLE HOLDING + SHAKING EXPOSED METHADONE BOTTLES; VERBAL TRANSACTIONS OVERHEARD

V. FACILITY APPEARANCE AND GENERAL SAFETY (14 NYCRR 1020.6, 1040.19)

—

THIS NOTICE OF DEFICIENCIES IS PROVIDED TO YOU PURSUANT TO THE REQUIREMENTS OF 14 NYCRR 1010.9 [illegible] WRITTEN PLAN FOR CORRECTION OF CITED DEFICIENCIES MUST BE SUBMITTED WITHIN TEN DAYS TO THE DIVISION, ATTENTION NEIL C. GROGIN, DEPUTY DIRECTOR, FISCAL AUDIT AND REGULATORY REVIEW, EXECUTIVE PARK SOUTH, BOX 8200, ALBANY, NEW YORK 12203

Charlotte Evans 2/9/90
Program Representative Acknowledging Receipt of Notice Date

MIKE YORIO 2/9/90
DSAS Review Team Leader Date

BETH ISRAEL MEDICAL CENTER FIRST AVENUE AT 16TH STREET, NEW YORK, NY 10003 (212) 420-2000

ATTACH. II

February 21, 1990

Mr. Neil C. Grogin
Deputy Director
Bureau of Fiscal Audit
and Regulatory Review
NYS Division of Substance Abuse Services
Executive Park South, BOX 8200
Albany, NY 12203-8200

Dear Mr. Grogin:

I am writing in response to your February 9, 1990 Notice of Deficiency.

On October 2, 1989 the Beth Israel Medical Center/Methadone Maintenance Treatment Program (BIMC/MMTP) contracted with the Laboratory for Chromatography, Inc. for urinalysis testing. Apparently this firm was not up to the task and was unable to process the quantity of specimens required in an accurate and timely fashion. Their attempt to deal with this by computerization was unsuccessful and on Janury 30, 1990 BIMC/MMTP was informed that the Laboratory for Chromatography had abrogated the contract.

The BIMC/MMTP has advised each clinic in our system to place a copy of the enclosed letters in patient charts and to add a note indicating that whatever few results were obtained were in fact questionable and could not be relied upon. Since that correspondence was not yet in the charts which were reviewed (15775, 119535, 59758, and 45179), I have enclosed a copy for your records. Immediately upon learning of this vendor's inability to continue, the BIMC/MMTP Materials Management Department began the process of rebidding the contract and the Divison of Substance Abuse Services was notified (see copy of enclosed letters).

BIMC/MMTP has strict antiloitering policies which are regularly reinforced to patients. Clinic staff frequently patrol the areas adjacent to the clinics to discourage loitering and a uniformed guard service keeps patients and others moving away from the building entrance. To underscore our commitment to this effort, programwide more than 1,000 additional patients have had their schedules increased to six times weekly within the last six months, in order to be sure that all take-home medication is properly handled. And finally, BIMC/MMTP has and will continue to discharge patients for excessive loitering or known diversion.

If a DSAS official again observes illegal activity, by one of our patients, or by anyone else, I would recommend that the police be called immediately to the scene. In addition, the MMTP clinic supervisor should be notified as soon as possible. While the supervisor will not confront the individual on the street, if a patient is indeed involved, appropriate disciplinary action will be taken promptly by the clinic.

If you need any additional information, you may contact me directly at (212) 420-2073.

Sincerely yours,

Nina Peyser

Nina Peskoe Peyser
Program Sponsor

Enc. (4)

:158

ADDENDUM TO WRITTEN TESTIMONY
PRESENTED TO THE SELECT COMMITTEE

MARCH 23, 1990

Robert G. Newman, M.D.

I have submitted written testimony addressing the specific questions posed by the Select Committee in advance of this Hearing. While I shall be pleased to elaborate on any aspect of that testimony, and respond to all questions, I shall limit my oral presentation to a brief commentary on the national NBC news broadcast last night regarding methadone "diversion."

It did not require a month-long Drug Enforcement Administration field investigation to demonstrate that there is a street market in methadone. Methadone "diversion" is a problem which I have acknowledged in prior testimony to this Committee, and in virtually everything I have said and written over the past 15 years. It indeed is a problem, and I have consistently offered a way to address it: provide potentially life-saving treatment on request to every heroin addict who wants and needs it, thus eliminating the demand for illicit methadone. Programs such as the one operated by Beth Israel do their very best to control the problem, and I am sure that law enforcement agencies do the same. But as long as medication known to be effective in helping addicts stop their heroin use is not available in a legal, medically supervised setting, none of our efforts will be productive.

While recognizing the importance of the methadone diversion problem, I must nevertheless question the focus of DEA on this particular aspect of the drug abuse problem in America. DEA's 1988 "investigation" involved deployment of Federal agents throughout the five boroughs of New York City for a full month. It resulted in the purchase of 8 grams of methadone. A problem, for sure. But weigh the magnitude of this problem against the hundreds of tons of heroin, cocaine, marijuana and other drugs that pour across our borders each year. Just last November, in the borough of Queens, law enforcement agents seized 6 tons of cocaine; two months earlier, in Los Angeles, well over 20 tons were seized. And it's been estimated that, at best, some 90% of drugs destined for the streets of our cities are not seized. One can't help but wonder if perhaps there's something strange about the priorities which are guiding our Federal officials.

What disturbed me most about last night's network news broadcast was the branding of methadone programs as "pushers." In the process, every employee who works in these programs was defamed. The comments attacked the most dedicated, compassionate health care workers with whom I have ever been associated - workers who provide help and hope to those who have been rejected by virtually all "helping" agencies in our society; workers who are not only committed, but extraordinarily effective.

The GAO study which you yourself commissioned, Congressman, determined that in the four New York methadone programs studied, heroin use was eliminated in 95-97%! This is a success rate which is so phenomenal that I would not even cite the figures if they did not emanate from a study of the totally impartial General Accounting Office. But these are the statistics that the GAO reported. And yet, the staff who account for these dramatic results were labeled "pushers" on last night's broadcast. It saddens me to an extent which I simply cannot express.

I accept without hesitation my responsibility to operate the very best treatment programs possible, and you have my commitment that I will meet this responsibility. In turn, I ask only that this Select Committee not lose sight of the fact that for the vast majority of addicts in our communities who desperately want, need and can be helped by treatment our great nation offers nothing by way of help or hope. This tragic reality is one that I cannot address. You can. I implore you to do so.

Thank you for your kind attention.

ST. MARY'S HOSPITAL OF BROOKLYN

ADDICTION SERVICE

PREPARED STATEMENT FOR THE SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL

METHADONE HEARING - NEW YORK - MARCH 23, 1990

This statement is prepared in response to a request made by the committee to address three (3) issues intended for discussion at a public hearing to take place at the U.S. Court of International Trade, Ceremonial Court, 1 Federal Plaza, New York.

The three issues on which specific focus is to be placed are the efficacy of methadone maintenance as a form of treatment the FDA/NIDA proposal for "minimum maintenance" and illegal methadone diversion.

We, treatment providers are aware that we each have an obligation to provide information that will benefit the continued search for solutions to problems associated with substance abuse.

You have already obtained statistical data which has aroused your attention to address the problem. The area of focus whether favorable or not will determine future trends and the outcome of treatment in New York City.

Methadone Maintenance As A Form Of Treatment:

We presently service over (1600) sixteen hundred patients. We note that having patients who have explored many treatment modalities, we are convinced that methadone maintenance treatment provides for many patients, the only and best form of treatment. Confidentiality regulations, family pressures and a lack of public awareness have prevented clinics from exhibiting their successes. We're adept at keeping statistics on recidivism rates, but our accuracy on positive trends leaves much to be desired.

Without a substitute, methadone maintenance as a form of treatment has established itself as a viable alternative to illicit drug use. We support its existence, and feel confident that expanding support services within the system will assist in improving the effectiveness of this form of treatment. Please see recommendations for providing additional services within the system. (Information from the Catholic Medical Center Substance Abuse Initiative Committee.)

"Minimum Maintenance": FDA/NIDA's proposal referred to in your letter has not been acceptable. The rationale of treating a population with greater illnesses with less services leaves unanswered questions, and theorizes that we're incapable of handling the complex problem of drug abuse. As a member state of the Northeast Methadone Coalition we recommend that **you revise the position paper presented on the subject** as time would not permit for giveing the details. The information is titled **"Interim Methadone Maintenance - Hearing Docket No. 88N-0444, February 28, 1990"**, delivered by the President, Mark Parrino.

ST. MARY'S HOSPITAL OF BROOKLYN

ADDICTION SERVICE

PREPARED STATEMENT FOR THE SELECT COMMITTEE
ON NARCOTICS ABUSE AND CONTROL

METHADONE HEARING - NEW YORK - MARCH 23, 1990

Assessing The Effectiveness Of Program Operations:

Over the years the drug abuse population has changed: thus patients entering treatment have changed. Patients come with an increasing number of problems. Multi-addictions, homelessness, AIDS and neglected health problems due to poverty and misguided focus fostered by drug use. These factors have necessitated assessing more closely operations, to assure the wide variety of problems are addressed in a manner that would benefit the patient population as a whole, and yet individually.

Assessing the effectiveness of our operations always has and continues to be an area of primary concern. Internal audits and peer reviews have been methods used for evaluating a clinic's effectiveness. Along with these are reviews from the New York State Division of Substance Abuse Services, Drug Enforcement Agency, the Food and Drug Administration and hospital staff from the Executive Office and Quality Assurance. Most recently the Joint Commission on the Accreditation of Health Organizations. Recommendations made are either incorporated or are reinforced to assure compliance or improvement.

Each of the agencies has standards, and if enforced the quality of operations should only improve. The hinderance for some, however, is the lack of standardized regulations.

This to some extent paves the way for mis-interpretation and confusion in carrying out policies which regulate operations. A lengthy process is involved in training new staff who are employed to work in substance abuse treatment. Treatment team supervisors have to constantly reinforce the following procedures. This job is not made easier be negligence - on their part.

Supplementing the program's continuous in-service training, is training offered by D.S.A.S. All treatment team staff benefit from these efforts. This is important to update staff persons with current trends in substance abuse treatment.

Methadone Diversion from Treatment Clinics and Clients In Treatment.
We were particularly concerned with DSAS's report on evidence of methadone diversion at 229 Powell Street also other deficiencies not stated in your letter of March 14, 1990. We recognize the importance attached to "methadone diversion" in the city. By no means do we intend to minimize this fact or defend its existence. However, we urge you to catch a glimpse of a larger picture and the other intense problems associated with this phenomenon.

There appears to be three contributing factors to diversion in our case:

1. Unlike many programs we operate within residential areas and behavior

associated with diversion is easily transferred from other areas within communities to the environs of the clinics which become meeting grounds for concentrations of persons who are otherwise an excluded group within and beyond the community.

The need is for smaller clinic sizes and greater community involvement in the treatment process.

Things we can do:

i. Broaden the range of community services we provide so that a positive link can be established as our image in the community improves.
ii. Design more family oriented thrusts in treatment. i.e. increase the level and quality of services associated with methadone maintenance treatment.

2.Some diversion reflects the problem of individuals who need to "test" themselves to see whether they are able to function without methadone maintenance treatment. There is in fact substantial family and community pressure for individuals in treatment to detoxify - often very prematurely. In addition the Methadone Maintenance Treatment Program model did not really anticipate detox, and post detox treatment needs and issues so the problem of "testing" is intensified by this ambiguity in the model.

ST. MARY'S HOSPITAL OF BROOKLYN

ADDICTION SERVICE

PREPARED STATEMENT FOR THE SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL

Dr. Johanna Kreek of Rockefeller University has argued that detoxification be carried out over a very long term - another basis of psychopharmacological data.

The need:

i. To develop more effective Methadone-to-Abstinence and post Methadone Maintenance Treatment contacts, and to develop more effective guidelines for granting and rescinding "**take home**" medication.

Things we can do:

i. Perhaps expand the hours for medication in order to propose a tighter "**take home**" policy.

ii. Encourage the development of post-medication intervention and treatment forums.

3. The most visible forms of diversion involve the problem of working with an "**excluded**" group. Even though we have observed the majority of persons in treatment stabilize their lifestyles and their ability to function adequately in society, there has perhaps been too little attention paid to the problem of social reintegration - a two-way process.
There remains strong social antagonism towards addicted persons, and this attitude poses serious obstacles to complete rehabilitation.
The need for public education remains very strong.

ST. MARY'S HOSPITAL OF BROOKLYN

ADDICTION SERVICE

PREPARED STATEMENT FOR THE SELECT COMMITTEE
ON NARCOTICS ABUSE AND CONTROL

METHADONE HEARING - NEW YORK - MARCH 23, 1990

What the clinic does to prevent diversion:

The clinic continues to focus on integrating the services of the community - namely community residents, the police department and its own staff to address the problem from all levels. This includes their awareness, and education of the patient population.

On an immediate basis the clinic's policy is to terminate any patient from treatment who is observed selling his/her medication. Interim methadone maintenance is not the solution to diversion. With less services to treat a complex problem it seems almost annoyingly simplistic to even consider, that the quality of treatment would be discussed in the same context.

Conclusion

The efficacy of methadone maintenance as a form of treatment, is undoubtedly one of the most successful methods. However, what has to be done, must be done to upgrade treatment team staff, to educate community persons, and to sensitize public officials to the many needs within the system. Staff and patients both need to work in better surroundings and safer buildings. Persons working in the drub abuse treatment system get the feeling that not only is the addict treated with disdain but also the people who support efforts to improve life for them.

We need to have you address more rigorously the need for public support for methadone treatment. We need to fight drug abuse on all fronts, not only on fronts that are pleasing, or comfortable. We must strive to eliminate the bias and ignorance that exists.

We thank you for allowing us to be a part of this Hearing to respond to your concerns. We assure you that we too share a number of your concerns and trust that together we can improve treatment for substance abusers. We remain committed to the task. Thank you.

Desrie B. Renaud, RN, MSHS
Administrator
St. Mary's Hospital of Brooklyn
ADDICTION SERVICE DEPARTMENT

Address to be delivered by: Bertram A. John, PhD, Staff Psychologist

ST. MARY'S HOSPITAL OF BROOKLYN

ADDICTION SERVICE

PREPARED STATEMENT FOR THE SELECT COMMITTEE
ON NARCOTICS ABUSE AND CONTROL

METHADONE HEARING - NEW YORK - MARCH 23, 1990

ATTACHMENTS - (See pg. 2 Methadone Hearing - March 23, 1990)

C.M.C. SUBSTANCE ABUSE INITIATIVE COMMITTEE

i. ACUPUNCTURE

ii. IN AND OUT PATIENT DETOX PROGRAMS

iii. AFTER CARE GROUP RESEARCH/EDUCATION AND PREVENTION

iv. VOCATIONAL/JOB DEVELOPMENT

NOTE: This material is the collective effort of a number of persons on the C.M.C. Substance Abuse Initiative Committee. Some items were brought to the committee through sub-committee members. Permission to use already published material may be necessary.

CATHOLIC MEDICAL CENTER
SUBSTANCE ABUSE INITIATIVE COMMITTEE

SUB-COMMITTEE REPORT
"ACUPUNCTURE"

Submitted By: D. B. Renaud

OVERVIEW

Acupuncture for methadone patients abusing crack and for methadone detox.

For methadone patients abusing crack there is no prescribed chemotherapy treatment for crack or cocaine abuse. Much of what has been done has been in the form of counseling.

Acupuncture may be a safe way to deal with the plight faced by a number of patients who fall into these two categories.

First a needs assessment will be made to determine feasibility.

NEED ASSESSMENT

To determine the patients who will benefit from treatment, counselors would be invited to select patients who are users of cocaine or crack.

However, to determine the eligible patient a criteria must be developed to identify the patient. These indicators will be listed and shared with the counselors - and other treatment team staff.

NUMBER OF PATIENTS

Initially, preparation should be made to treat 100 patients. That would allow us to treat 25 patients from each clinic. This quantity would allow staff persons to monitor their patients to determine to what extent treatment received is positive or negative.

Treatment team staff will receive training from someone knowledgeable on the subject of acupuncture. This would allow persons to carry out needed follow-up.

WHAT IS ACUPUNCTURE

Acupuncture is an ancient healing art in which small pins are placed at "active points" on the body to bring about a rebalancing of the mind and body. Like many forms of natural medicine, it focuses on mobilizing the mind/body's own healing forces. In this way the mind/body is aided in it's attempt to bring itself to the most optimal possible state of health without the long term dependence on medication.

WHO'S ELIGIBLE

1. Methadone patients in treatment.
2. Patients on detox schedule.
3. Patients abusing crack/cocaine.
4. Other identifying features: - to be determined: -
    a. age
    b. lenght of time in treatment
    c. sex
    d. medical problems
    e. attempts at other treatment
    f. repeats - similar treatment

Other Components Needed

1. Nutrition component - Nutritional guidance will allow acupuncture patients to maximize health.
2. Staffing - to be determined.
3. Cost of project - to be determined.

OUTLINE

- Case identification - to assure efficient and effective flow of referrals from clinics.
- Case management - to assure flow of referrals and follow-up of case.

  Comprehensive treatment services - medical.

  - These standards should be developed to determine what type of assessment and follow-up is done.
- Psychological counseling - To what extent can these services be provided and to what extent - is it necessary.
- Psychosocial counseling, advocacy and educational services to provide necessary or needed support the patients require.

PROCESS OF THERAPY

This outline will explain what treatment process will take place with the patient from referral, admission and through discharge.

- If stages are to be used - What takes place at each - and the desired outcome along with it if outcome was achieved and if not, why.
- Data collection and research study if feasible.
- Documentation and production of final/ongoing report - publish.

- Special challenges faced by -

ACUPUNCTURE DETOXIFICATION TRAINING

Described or outlined as: -

Introductory Phase - Sessions with prospective clients.

Topics - Use of case study

Demonstration of ear puncture

Examples of usefulness of acupuncture

Question and answer period

Use - Materials, literature, slides, etc.

Qualified instructor.

Visits - tour of facilities.

Meetings - to determine what's needed.

Time?

/

CATHOLIC MEDICAL CENTER
SUBSTANCE ABUSE INITIATIVE COMMITTEE
SUB-COMMITTEE REPORT II

"ACUPUNCTURE"

Submitted By:
Desrie B. Renaud - Chairperson

Members - Dr. Suh
Dr. Wong
V. Williams, RN

MINUTES: FEBRUARY 14, 1990

Present: Dr. Wong, Dr. Suh, Ms. Williams, RN
Ms. D.B. Renaud.

General Statement

Ms. Renaud explained the reason for the meeting, it's purpose and what was expected to be the outcome. With that in mind a number of items were discussed and the following is a report.

TRAINING - Dr. Wong felt that a one (1) week training of MDs would be appropriate. However, other professionals could be trained within a month. The method would be by map demonstration and practice.

ADMISSION - The criteria for admission would be a patient who is willing and highly motivated to want to enter treatment. Patients detoxing from methadone - a patient on cocaine/crack.

a) Age - although an age limit would not be set, it is noted that younger patients do better.

b) Health Assessment - There are no health problems that would disallow the use of acupuncture. However, a thorough assessment of a patient's physical condition will be made.

c) Consent - Patients will be required to sign a consent for treatment form.

d) Counsel - Each patient will be given an overview of acupuncture treatment.

Method - Patients will be required to have daily toxicology - urine will be collected daily.

Ear - Points used for Alcohol, Drug Abuse, Smoking, Cravings are the same. Procedure - for needle insertion once a day for one half of an hour or same every other day - reduction after review of patient.

Lenght of Stay - The length of stay will be dependent upon the patient. This may be 2 - 3 weeks.

Research - It is recommended that during this period of treatment, a component should be built in.

Licensure - We will obtain information whether licensure of Federal, State or City is needed.

Information- Dr. Wong indicated that if additional information is needed that she will be willing to give same, and also to make available speakers who are experts on the subject.

Attachment - Dr. Wong distributed the attached article.

Acupuncture & Electro-Therapeutics Research, The International Journal, Vol. 1, Nos. 1, 2 & 3, 1975
Pergamon Press, New York, Oxford, Toronto & Sydney

Wong

ELECTRO-ACUPUNCTURE FOR DRUG ADDICTION WITHDRAWAL SYNDROME, PARTICULARLY METHADONE, & INDIVIDUALIZED ACUPUNCTURE TREATMENTS FOR THE WITHDRAWAL SYNDROMES OF DRUG ADDICTIONS AND COMPULSIVE HABITS OF EXCESSIVE EATING, DRINKING ALCOHOL AND SMOKING (No. 18)*

Yoshiaki Omura, M.D., Sc.D.

Director of Medical Research, Heart Disease Research Foundation, 963 Essex St., Brooklyn, New York, 11208;
Visiting Research Professor, Department of Electrical Engineering, Manhattan College,
Riverdale, Bronx, New York City, N.Y. 10471;
Visiting Professor, University of Paris V & VI;
Acupuncture Program for Drug Addiction Detoxification at Lincoln Hospital, NYC.

With the cooperation of Drs. Michael Smith, Fung Wong, Franklin Appfel, Richard Taft,
Than Nyint Mintz, Jasu G. Mehter, J. David Lefkowitz, Mr. Ricci Murphy, administration, staff,
former patients and community volunteers at Lincoln Hospital, New York City.

Clinical investigations by the author into the relationship between abnormal Skin Temperature, abnormal Electrical Impedance (Z_f), abnormal d.c. Electrical Resistance (R_f) of body surface and its time course in reference to abnormal conditions or diseases has led to the following simple, individualized and effective Auricular Acupuncture method useds in treatment of Withdrawal Syndromes of drug addiction from Methadone, Heroin, etc. In contrast to the fixed location Auricular Acupuncture method developed by Drs Wen and Cheung for Withdrawal Syndromes, this author determined the most effective Acupuncture points or areas by measuring relatively low Z_f or low R_f points or areas and abnormal Skin Temperature (particularly increased Skin Temperature) points or areas using a battery-operated impedance or d.c. ohm meter and electronic thermometer with short response time (less than 80 msec). Withdrawal Syndromes of Methadone and Heroin, such as muscle and joint pain, muscle tightness, abdominal cramps or discomfort, nausea, diarrhea (or constipation), insomnia, irritability, anxiety, impotence, inability to concentrate alternative appearance of coldness and chill sensations with shivering, followed by hotness with sweating, etc., as well as associated excessive smoking or drinking alcohol are treated at the Auricular Acupuncture points or areas determined above, either by safe and effective electrical stimulation through Acupuncture needles or surface electrodes as frequently as needed, or by inserting and leaving the "Intra-dermal Needle" in dermis or subcutaneous tissue in parallel with the skin of the ear, covered by a bandaid for periods of 1-8 weeks and having the patient massage both sides of the ear over the needle for an average of 4 times daily, lasting 5-20 minutes each or as required. Patients who are sensitive to needles can massage metal balls (with or without magnetization) held in place on the ear by a bandaid. Even small hard beads or grains, such as raw rice, can be substituted to stimulate the desired effects. Additional effective body Acupuncture was used in patients when certain symptoms did not disappear. For example, for lower-abdominal discomfort, pain or cramps (including menstrual problems), manual or electro-acupuncture was given to Sp. 6 (*San Yin Chiao*) in both lower legs. For most gastro-intestinal problems, particularly for upper-abdominal pain, gastric pain, or constipation of diarrhea, acupuncture was administered to the St. 36 (*Tsu San Li*) area, near the knee. Either manual acupuncture or electro-acupuncture was given, often with dramatic results.

While studying the effects of acupuncture on Withdrawal Syndrome of drug-addicted patients, the author found not only an improvement in symptoms but also a significant decrease in the number of cigarettes smoked (50-90% within the first week) and the amount of alcohol consumed (30-70% within the first week). In the majority of patients, the maximum weight loss was observed within the first week of treatment. Such weight loss was usually in the range of 2-10% of the pre-acupuncture body weight and manifested itself within 7 to 10 days, with no medicine given and no control of diet. Once the maximum

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* This paper was presented at the meeting of the New York Society of Acupuncture for Physicians and Dentists, Inc., held in New York City, January 11-15, 1975.

weight loss plateau was reached, the body weight stayed at the same level during the rest of acupuncture treatment.

In all of these cases, treatment was administered by manual or electro-acupuncture, administered daily, primarily on the ear, or by intra-dermal acupuncture, imbedded in the skin of the ear and massaged daily by the patient, or by the use of the metal balls–although the effects here were usually less significant than with the former 3 methods, unless the number of the balls increased significantly. Electro-acupuncture was more effective when it was passed between the two ears. Considerable improvement in the Withdrawal Syndrome usually appears within a few to 30 min, with a frequency of somewhere between 40 and 250 pulses/sec (the lower the frequency the longer the effects appear to last), with pulse duration of about 300 μsec or less and voltage delivered to the body tissue of 1.5 to 6 V. The output impedance of the pulse generators used for this study varied between 50Ω to 25kΩ. To evaluate and compare the effectiveness of of acupuncture among different individuals with different body weights, the author introduced the following series of indexes:

Detoxification index for evaluating the effectiveness of acupuncture or other means of treating drug addiction

$$\text{(1)}\quad \text{Detoxification Index} = I_{\text{detox}} = \frac{\text{Reduction in Maintenance Dose of Drug}}{\text{Body Weight} \times \text{Days Required for Detox}}$$

Weight loss index for evaluating the effectiveness of acupuncture or other means of reducing weight for given periods of time

$$\text{(2)}\quad \text{Weight Loss Index} = I_{\text{weight loss}} = \frac{\text{Loss of Body Weight}}{\text{Body Weight} \times \text{Days Required for Loss}}$$

Smoking reduction index for evaluating the effectiveness of acupuncture or other means of reducing the number of cigarettes or other habit-forming substances smoked

$$\text{(3)}\quad \text{Smoking Reduction Index} = I_{\text{smoking reduction}} = \frac{\text{Reduction in Number of Cigarettes Smoked}}{\text{Body Weight} \times \text{Days Required for the Reduction}}$$

Alcohol reduction index for evaluating the effectiveness of acupuncture or other means of reducing alcohol Consumption

$$\text{(4)}\quad \text{Alcohol Reduction Index} = I_{\text{alcohol reduction}} = \frac{\text{Amount of Reduction of Alcohol Consumption}}{\text{Body Weight} \times \text{Days Required for the Reduction}}$$

A preliminary study in Lincoln Hospital was made in 1974, using the fixed lung point method of Wen and Cheung of Hong Kong on about 100 patients. In spite of the doctors claim of nearly ideal results, much less success was achieved than with these individualized methods of treatment developed by the author, applied in large scale clinical treatment since 1974 of more than 200 patients at Lincoln Hospital alone. Some of the patients' CBC, blood chemistries and urine analysis was carried out before and about 20 h after Acupuncture, and the details and analysis of this work will be published in the near future.

In addition, the author's personal study of more than 300 patients before 1974–with no pre-knowledge of the patients' medical histories or present problems–demonstrated about 60% accuracy in diagnosis by examination of the ear alone, based on Dr. Paul Nogier's organcorrespondence theory of the ear. These low-impedance points of the ear were found to be usually more sensitive to electrical, mechanical or thermal stimulation than were surrounding tissue. However, in treating the patients with Auricular Acupuncture, regardless of the diseased organ corresponding to the indicated point on the ear, electro-acupuncture given on such low-impedance points or areas of the ear provided more significant effects than acupuncture given on the corresponding organ points or particular fixed points where electrical impedance was normal or very high.

In general, in applying electro-acupuncture between the ears, the maximum effects can be obtained by placing the electrodes at the lowest electrical impedance point (or area) or the area of highest skin temperature or at the area of the ear corresponding to the shoulder. Electro-acupuncture given between the ears is shown to be very effective in treating much of the Withdrawal Syndrome of Drug Addiction. Its possible mechanism involves so many factors–such as effects on vagus nerve stimulation in the ear as well as the effects of stimulating the central nervous system including caudate nucleus–that further research, on both humans and animals is urgently needed. Thus it is concluded that Auricular Therapy has definite clinical value but requires much further study.

(This research is supported in part by the Heart Disease Research Foundation, since 1972)

References:

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February 7, 1990

ST. MARY'S HOSPITAL IN-PATIENT DETOXIFICATION PROGRAM

Submitted By:

Joyce Tucker, Chairperson
Ray Olisa, Member
Program Initiative Sub-Committee

ST. MARY'S HOSPITAL IN-PATIENT DETOXIFICATION PROGRAM

Background. We are in the midst of an almost intractable plague. Cocaine (and with it crack), once an esoteric word, is now the bane of our society. Its distructive impact is felt by almost all of us. Our streets are terrorized. Parents seek ways to shield their children from this drug of doom. Politicians inveigh against the crime arising from the use of cocaine - be it on the demand or supply side. And health service providers, emboldened by their experience in combating heroin addiction, are now seeking effective cocaine addiction treatment.

A few cocaine detoxification programs have sprouted up in a number of communities. Interviews with some individuals who were treated by the new programs quickly exposed their limitations. Principally, there are three. First, the programs have a poly-drug detoxification orientation, dealing with drugs ranging from barbiturates to cocaine. Secondly, the length of stay is limited to seven days. Thirdly, they offer very little supportive therapy or none whatever. After the completion of treatment, the patient has no where else to go, and relapse seems almost inevitable.

Program Description: We are planning to launch a 24-bed in-patient cocaine detoxification program which will be sited at St. Mary's Hospital.

Cont'd

Patients will be detoxed primarily from cocaine. Characteristically, it differs from the existing programs in that it takes into account their limitations in defining the range of services it will offer. First, the program's length of stay will be 14 days. Secondly, as was stated earlier, only cocaine detoxification will be undertaken. Thirdly, upon completion of the 14-day treatment cycle, the patient will be referred to a companion project, an out-patient drug-free program (to be elaborated on later) for intensive therapy. It is planned that the patient will stay in treatment in the out-patient component for a maximum period of six months. Pre-admission treatment plan would include goals, objectives , and a discharge plan all of which would be clearly delineated. Lastly, the detox program would also meet the need of the four Addiction Service Department clinics, which are continually searching for programs to treat their patients with cocaine problems.

Staffing. We envisage a start-up staff of one medical director, one psychiatrist, one social worker, three staff nurses and one secretary/clerk, who will also be responsible for billing.

Admission Criteria - These would include:

1. History of crack and cocaine use
2. Physical examination
3. Urine toxicology test

Sources of Referrals - Walk-ins
M.M.T. Programs
Court/Probation Department
Department of Social Services

ST. MARY'S HOSPITAL OF BROOKLYN

IN-PATIENT DETOXIFICATION PROGRAM
(AN ADDENDUM)

OBJECTIVES

Objectives are as follows:

1. To seek and attract into treatment individuals who are currently addicted to cocaine.
2. To offer detoxification services to patients who are abusing drugs (cocaine) in the four methadone clinics operated by St. Mary's Hospital.
3. To offer the addict an opportunity for long-term rehabilitation through referral to programs that meet their needs.

SCOPE OF SERVICES

The limited period of time in which the patients are in treatment necessitates that (1) services be tailored to meet their immediate needs and (2) priorities be set as to which of the needs are to be addressed first. Foremost among these needs are the patient's dependence on cocaine - his quest for satisfying the psychological hunger that results from not having his regular "fix". Weaning him off this habit through the use of non-narcotic chemotherapy becomes the primary service offered to the patients upon admission. Concurrently, the clinic will also provide the following: -

1. Medical examination and referral within the hospital or to other institutions.
2. Psychiatric care/counseling
3. Counseling
4. Intermediate - Term Referral

The initial thrust of the staff's effort is to deal with the discomfort, tension, fear and anxiety arising from the substitution of non-narcotic drugs (to be specified later) for cocaine. This will be accomplished through medical, psychiatric and psychosocial counseling. Medical examination and counseling will be performed at the same time and referrals made as appropriate. Psychosocial, family and vocational counseling will be made after the patient has begun feeling confortable and is now at ease with himself and the staff; and intermediate or long-term referral will follow. In fact, staff will ensure that the requirements for admission to the outpatient clinic are met before the patient is discharged. Ideally, there will be no interruption in treatment, for arrangement will be made for the patient to be picked up and transported directly to the out-patient unit on the day of discharge. This continuity of treatment will give the patient a clear message: that our ultimate goal is his long-term rehabilitation and that we are making this possible for him through referral to a program best suited to treat him.

NEEDS ASSESSMENT

The in-patient detoxification unit will accept applications from eligible individuals whether they are in treatment or not. The most important for substance abuse. It is the second most densely populated borough with 2,230,736 residents. Twenty-four percent of the residents live on income below poverty level. Forty-five percent of Brooklyn residents, age 25 and over, did not complete high school. If the hypothesis that there is a correlation between the incidence of substance abuse and poverty is valid, we can easily extrapolate from this that there are sizeable number of substance abusers, including cocaine in Brooklyn.

However, apart from the population at large, there is also a need for a specific group of individuals who seem to have not found a satisfactory alternative. These are the patients in treatment in the four methadone clinics operated by St. Mary's Hospital. As of January, 1990, there were 1,647 patients tested positive for a variety of drugs, including cocaine which 37% of the roughly 70% who tested positive - abused. It is logical to conclude from this that the methadone clinics in Brooklyn, which are not operated by St. Mary's Hospital, have the same experience.

Most of the abusers often need in-patient detoxification for which there is an acute shortage. The Heatlh Systems Agency of New York City, in its June 1985 Report on Substance Abuse Plan for the City of New York, estimated that 133 in-patient detox bed slots were needed in Brooklyn for narcotic and non-narcotic abusers. The report further stated that only 37 of these slots were at the time available. Many patients withdrew from treatment prematurely, invariably to their own detriment, due to the long delays in obtaining treatment slots in in-patient detoxification facilities.

requirement, in fact the sine qua non criterion, is the history of addiction. Potentially, there are many individuals in our communities who meet the program's requirements. For example, Brooklyn has a growing population at risk for substance abuse. It is the second most densely populated borough with 2,230,736 residents. Twenty-four percent of the residents live on income below poverty level. Forty-five of Brooklyn residents, age 25 and over, did not complete high school. If the hypothesis that there is a correlation between the incidence of substance abuse and poverty, we can easily extrapolate from this that there are sizeable number of substance abusers, including cocaine in Brooklyn.

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STAFFING AND TRAINING

The in-patient detoxification clinic staff will be composed of the following: -

1	Medical Director
1	Administrator
1	Psychiatrist
3	Staff Nurses
1	Social Worker
1	Secretary/Billing Clerk

Training will be scheduled in phases and separately for the various disciplines. A maximum of two weeks will be allocated for orientation and training, and eligible applicants will be admitted to treatment the following week. The type of training and format are being assessed. Where possible, only individuals with relevant experience in in-patient detoxification will be hired initially.

HOURS OF OPERATION

Of necessity, the hours of operation will be 24 hours. Admissions, medical screening and counseling will be conducted in the day, usually between 7:00 a.m. and 3:00 p.m. Since there are only three nurses on staff, we plan to have one nurse on each shift. The Hospital guard will handle security matters, particularly during the night, with an eye to discouraging drug transactions between the patients on the one hand and drug traders who might be inclined to tempt the patients.

St. Mary's Hospital Outpatient Detoxification Program

Overview. An eye-riveting headline in one of our daily premier newspapers read: "World Drug Crop Up Sharply Despite U.S. Effort." The accompanying article then cited a report prepared and submitted by the Department of State to Congress, which estimated that "from 1988 to 1989, the production of opium increased by a staggering 47 percent. Coca production increased 12 percent among the four coca-producing countries - Peru, Colombia, Bolivia and Ecuador, while hashish rose 16 percent. Estimates of marijuana production were up 210 percent...".[1] Since 1985, opium production has increased 187 percent, coca 43 percent and marijuana 502 percent. Mr. David L. Westrate, Assistant Administrator for Operations, the Drug Enforcement Administration, reported to the Congressional task force that heroin might eventually become a bigger worry than cocaine.

Clearly, looking at the substance abuse problem from the supply side, all efforts at interdiction by sophisticated United States' war ships and aircraft notwithstanding, we must of necessity conclude that progress has been minimal at best. Increases on the supply side inevitably lead to corresponding increases on the demand side, defined generally to include our schools, streets, the buildings in which we live - in short, anyone who is addicted to or a purveyor of drugs.

[1] World Drug Crop Up Sharply Despite U.S. Effort," New York Times, March 2, 1990, p.1

As a consequence of the startling increase in the availability of drugs, starting with cocaine and heroin, we now see a world that is not very much to our liking, characterized by a growing number of men and women, who are disenfranchised, crime prone and violent, unproductive, and indifferent to their own condition and that of society. They are at the same time the most malnourished and in need of medical care. We are horrified, almost awe-struck, by the enormity of the problem arising from their drug addiction.

We are further confounded by the apparent suddenness with which this problem descended upon us and are lulled into believing that it is a peculiarly mid-twentieth century phenomenon.

Far from being a novelty, narcotic addiction has been with us for generations: "... the United States had a large number of opiate addicts in the period between the Civil War and the passage of the Harrison Act, which limited the availability of drugs in 1914 ... They regularly injected morphine or took opiated medicine orally ... Most were knowingly addicted, of course, and addiction was a matter of great individual concern."[2] The estimated number of addicts, who were cut off from their traditional sources of supply (physicians) was approximately 300,000 at the time the Harrison Act was passed. To treat the addicts who were cut off from their source, a number of cities set up maintenance clinics, the prototype of our present day methadone clinics (one could argue), which numbered 40 at one point. Community antipathy, combined with incessant pressure on local governments by abstinence advocates, who saw heroin maintenance as a form of addiction, forced the clinics to close. The last one was closed in 1923.

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[2] James V. DeLong, "Treatment and Rehabilitation," Dealing With Drug Abuse (New York: Praeger Publishers, 1972), p. 175

Meanwhile, enforcement of the Harrison Act continues unabated. About 25,000 doctors were arrested and 5,000 jailed between 1914 and 1938. The Federal Bureau of Narcotics estimated that there were 20,000 addicts in the United States in 1945, down from the 300,000 estimated at the time the Harrison Act was passed in 1914. Whether the Bureau of Narcotics estimate was accurate or not is debatable. What is important is that the addiction problem is still with us again in full force, this time more entrenched and at once diversified, and affecting almost every household.

Cocaine and heroin abuse appear to be doubling every few years, with both switching positions with respect to popularity. As reported by hospital emergency rooms, (please see Table 1), heroin was the second drug of preference, next to alcohol in 1984 in New York State out of 190 drugs.[3]

[3] U.S. Department of Health and Human Services, Annual Data 1984, Data From The Drug Abuse Network, Publication No. (ADM) 85-1407 (Washington, D.C., 1985), p. 68

Table I - Drugs Mentioned Most Frequently By Emergency Rooms

Drug Name	Number of Mentions	Percent of Total Episodes
1. Alcohol	20,994	21.86
2. Heroin	11,944	12.44
3. Cocaine	10,152	10.57
4. Diazepam	8,316	8.66
5. PCP	5,584	5.81
6. Aspirin	5,312	5.53

The popularity of the drugs and hence the frequency of abuse went up dramatically according to the 1987 data shown in Table II[4], with cocaine being the most popular of 234 drugs:

Table II - Drugs Mentioned Most Frequently By Emergency Rooms

Drug Name	Number of Mentions	Percent of Total Episodes
1. Cocaine	46,331	31.57
2. Alcohol	40,644	27.69
3. Heroin/Morphine	18,566	12.65
4. Marijuana/Hashish	10,083	6.87
5. PCP	9,545	6.50
6. Diazepam	7,277	4.96

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[4] U.S. Department of Health and Human Services, Annual Data, 1987, Data From The Drug Abuse Warning Network, Publication No. (ADM) 88-1584 (Washington, D.C., 1988) p. 26

The 1987 Update to the Statewide Comprehensive Five-Year Plan indicates that more than 260,000 people, about 2 percent of the population, were considered narcotic abusers in New York State in 1987.[5] Young adults, from age 18 through 34, represented the largest group of abusers and accounted for 70.9% of all abusers. The data from the same publication showed the following with respect to heroin and cocaine:

Heroin - "... admissions of heroin addicts to New York City Department of Correction's detoxification unit at the Riker's Island facility remain at exceedingly high levels - over 15,000 admissions in 1985 and 1986."

"The New York City Correction Commissioner reports that of the 100,000 inmates passing through the City jails, more than 25,000 are addicted to heroin."

"... over 40 percent of admissions to State-funded treatment programs in New York City and over 20 percent of admissions to programs in the rest of the State report heroin as their primary drug of abuse."

Cocaine - "Estimates of narcotic-abusing population - mainly heroin abusers - have remained at 260,000, with 200,000 narcotic abusers estimated in New York City and 60,000 estimated in the rest of the State." Regular (weekly or more frequent) use of cocaine is a phenomenon that has increased

[5] State of New York, Division of Substance Abuse Services, 1987 Update to the Statewide Comprehensive Five-Year Plan, Report to Governor Mario Cuomo and Legislature (Albany, New York: 1987), p. 22

dramatically in the past few years. The number of regular cocaine abusers more than doubled - from 45,500 to more than 96,400 between 1981 and 1986. During the same period, the number of heavy cocaine abusers tripled from 19,300 to 65,500, according to the survey.

"... arrests involving cocaine continue to be an increasing proportion of the arrest activity of the New York Police Department's Narcotic Division. In 1983, these arrests represented 29 percent (5,496) of drug arrests; in 1984, 30 percent (5,651); in 1985, 33 percent (7,364); and in 1986, 54 percent (14,987)."

"Admissions to State-funded treatment programs with cocaine as the primary drug of abuse have increased markedly. For New York City programs, these admissions increased 87 percent between 1985 and 1986 (from 4,348 to 8,140). For programs in the rest of the State, these admissions increased 56 percent during the same time period (from 2,648 to 4,136)."

Objectives - In view of the magnitude of the problem and fully aware of the limitations of any one group of people or health facilities to solve the addiction problem, this program sets out to accomplish a clearly delineated set of objectives:

1. To seek and attract heroin and cocaine addicts into treatment.

2. To offer detoxification services to individuals who are abusing heroin and cocaine and are consequently addicted to them.

3. To offer addicted patients opportunity for long-term rehabilitation through referral to programs appropriate to their treatment needs.

4. To provide screening and follow-up as indicated for acute chronic conditions whether related to addiction or not.

Scope of Services - In 1971, the New York City Health Services Administration launched a detoxification program. Contracts were signed with a number of hospitals and non-profit institutions for the day-to-day operations of the clinics. By 1973, the Health Services Administration Ambulatory Detoxification Program was composed of 10 units, broken down as follows:

Borough	Contracting Entity	Unit Operated
Manhattan	Hospital for Joint Diseases	1
	New York Medical College	1
	Harlem Hospital	2
	Bellevue Hospital	1
	NENA	1
	Sub-Total	6
Bronx	Bronx Lebanon Hospital	1
	Morrisania South-Bronx	1
	Sub-Total	2
Brooklyn	St. Mary's Hospital	2
	Grand-Total	10

The ambulatory detoxification clinics were initially popular not only with the primary beneficiaries, who were the addicts, but also with long-term treatment facilities, which found them as a conduit for new admissions. In time, the novelty of the clinics wore out, making them less attractive. This was exacerbated by the paucity of supportive services, beyond and as a supplement to chemotherapy, that the patients needed. Ultimately, community hostility to methadone clinics, more relentless and strident then, combined with inadequate funding, led to the phasing out of all the clinics by 1975.

The integrated detoxification program will by no means be a clone of the 1970's vintage. For one, it will be multimodal in character, with equal stress on its three basic components: heroin detoxification, cocaine detoxification, social counseling. The social counseling part will be diversified, ranging from intensive one-to-one therapy to family counseling. The approach to treatment will be holistic. A weakness in this category will spell the doom of the other functions. Consequently, the social functions will be performed by a cadre of qualified, competent and motivated staff who will intuitively know that their efforts and performance are vital to the success of the program.

Some of the services to be provided by the program include the following:

1. Medical examination including routine diagnostic tests
2. Medical referral for further diagnostic and therapeutic care
3. Individual therapy
4. Group therapy
5. Family therapy
6. Vocational counseling and placement
7. Recreational and cultural activities, including calisthenics, medication, aerobics
8. AIDS prevention lectures
9. Long-term referrals

The program's objective is to re-orient the patient from his feeling of low self-esteem to one of personal worth, from his distorted perception of the people and things around him to one in which his perception of life is more in consonant with the way it is seen by the average person.

Lastly, we plan to work with the patient to the point that he feels he is in control of his life, to a large measure, and he is no longer a chaff to be blown away by the hostile wind buffeting him.

The clinic will have a capacity of 150 patients. This maximum capacity will be attained within six months. Two broad groups of applicants will be accepted - those who are already detoxified by other institutions from either their cocaine or heroin addiction and those who are still abusing and are in need of treatment. The first group of patients will be admitted to the aftercare component of the operation and the second group will be detoxified before being phased into the aftercare component. Walk-ins and referrals will be accepted.

The patients, whether detoxified or not, will be divided into two groups, Phase I and Phase II, and assigned accordingly. All applicants who are abusing drugs at the time of admission will be assigned to the Phase I group. Conversely, no new admissions will be assigned to the Phase II group, which is arrived at as an indication of the patient's progress in treatment. In Phase I, emphasis will be placed on one-to-one counseling in an effort to induce the patient to accept the reality of his drug problem. In this phase, the focus will also be on lectures, educational films interspersed with recreational activities, including low aerobics, or easy-going relaxation techniques, calisthenics, group discussions about cocaine and other substance abuse drugs. This phase provides a forum for the patients to play an active role in the dissection of their problems and their peers', interact with other patients and the staff, and learn more about themselves and their life.

Phase II represents the period in treatment when the patient is vocationally assessed. At this point, not only is the patient's drug problem being discussed and addressed vigorously, but the patient is also being prepared for his eventual discharge from the program or re-entry into society. The vocational counselors' and social workers' mettle will be more than tested at this juncture. Specifically, they will be concerned with the following:

1. Separation planning for the patient
2. Referral and placement
3. Aftercare follow-up and re-entry into the program, either temporarily or for the duration of the term.

Staffing and Training. The program's initial start-up staff consists of the following:

1 Psychologist
6 Social Workers (Counselors)
3 Counselors
1 Clerk Typist
1 Part-Time Physician
1 Administrator
1 Assistant Administrator
3 Vocational Counselors
4 Registered Nurses
2 Custodians
2 Security Guards

Provisions for training the staff before patients are admitted to treatment are being seriously considered.

Hours of Operation. The clinic hours are 7:00 a.m. - 7:00 p.m., Monday through Friday. However, the feasibility of opening the facility on Saturday and Sunday is being investigated. The staff will be staggered. One shift will work from 7:00 a.m. to 3:00 p.m. and the second shift from 11:00 a.m. to 7:00 p.m. The physician's and psychologist's hours will also be staggered to accommodate working patients.

Location/Space. We have not located a site for the operation. However, we envisage a facility which is located in a fairly stable, clean and accessible community. At all cost, a run-down building in a drug-infested community would be avoided. We are convinced that there is a linear relationship between the patient and his environment. Improve the latter, and you will have a patient who will be amenable to therapy. This is the compelling reason for seeking a site that is conducive to treatment.

Funding. Direct funding is being explored presently. This would constitute the seed money necessary to get the project beyond the drawing board stage. In addition, revenues will be obtained from three other sources: 1) Medicaid, 2) Self-pay and 3) Third party reimbursement (Blue Cross, GHI). The total revenues obtainable from these sources in the first year should be sufficient to cover expenditures, or the project would not be fiscally viable.

Work Plan. The specific tasks involved will be outlined in the course of time, accompanied by a projected start-up date, time tables for completing the major tasks, and milestone charts indicating days, weeks, etc. necessary to complete the tasks.

CATHOLIC MEDICAL CENTER
SUBSTANCE ABUSE INITIATIVE COMMITTEE
SUB-COMMITTEE REPORT
AFTERCARE GROUP - RESEARCH, EDUCATION, PREVENTION

Submitted By: T. Campbell
Clinic Director
Powell Street

SUB-COMMITTEE REPORT

2/8/90

Committee Members: T. Campbell, G. Frost-Meredith, B. John, E. Callendar, W. Walsh (Excused)

I. Discussed Titles

"Comprehensive Family Services Center"
"Multi-Service Family Center"

II. Services to be Offered:

Day Program Services and Evening Program

To Clinic population
To Community.

FAMILY SERVICES:

1. Counseling (1 on 1) individual group, family focus
2. Groups - (therapy, support and speciality i.e. "women's" (parent/child) "children at risk (Cosa)" "Cocaine/Crack" "Men's Issue" "Transitional" etc. "Traditional couples" "Atypical couples" "Drug-free/Detox initiation groups."

3. Referrals -Linkages

4. Children's (Family) Services:

-Parenting Skills Workshops
-Counseling Program (1 on 1), Indiv; groups
-Day Care Program
-After School Program Including Educational Workshops
-Recreational/Social Activities
-Tutorial Services.

B. COMMUNITY SERVICES: Outreach

1. Educational outreach (Prevention/Risk-reduction etc.)
2. Workshops/Presentations, at outside Agencies/on-site
3. Educational - GED, Nutritional, Vocational, School outreach.

ADDICTION SERVICES:

1. Expansion of current Addiction Services to include
2. Newly Designed program of group for CRACK/Cocaine Treatment.
3. Groups (Therapy, support) Includes Drug-free initiatives

Addiction Services cont'd..

and detoxification groups.

HIV/RISK REDUCTION SERVICES:

1. Prevention Education
2. Referrals for Testing and link to on-site Program or at D.H.
3. Pre-post Counseling.

III. RELEVANT ISSUES DISCUSSED:

1. Community Liaison Officer
   -Utilize existing strengths in Community, i.e. churches and schools, Health Fairs, "Spark".
2. Search for Specific Funding i.e.
   -Pregnant Addicts
   -C.O.S.A.
   -Lesbian Women/Gays
   -Literacy Skills
   _HIV Services
   -Parenting Workshops/Services.

3. SITES:

   Queens (MIH) and SMH
   Require one or two sites, at first one, expand to both Sites later or go for two sites initially.

4. Needs Assessment (To be done later).
   Needed Stats:

   1. Target populations from respective Community Boards of Catchment areas).
   2. At risk (HIV) D.H., DSAS.

5. SITES'SPECIFICATIONS:
   -group rooms (groups and/or Teaching)
   -Individual Counseling Rooms
   -Recreational Areas
   -Conference Room (s)
   -Kitchen
   -Auditorium/Theatre (small),(presentation, school audiences, etc.)

   RESOURCE CENTER:

   (Library, Indexes, Directories, Resource Books, Research Tools, Computer Search Data etc.

Resource Center cont'd..

-Counseling Areas (Sound proof)
-Children's Areas - Consider on first level, Lighting ventilation/Special furniture etc.

EACH SERVICE MAY REQUIRE:

Special Type Room- i.e. therapy rooms, medical rooms (Exam Room)
-Conference Room (Screen, Film etc.)

IV. STAFFING /FUNDING (1 year plus projected 2nd/3rd year)

a. Educational Focus
b. Child/Community Focus

V. STAFF - SUGGESTED:

Director
Assistant Director
Supervisor
C.S.W.'s (1-20) (With group work experience)
Teachers (1-12/15)
R.N. (R/N Education
Nutritionist
Childcare Workers
Vocational Counselor

CLERICAL SUPPORT Includes Receptionists
HouseKeeper/Janitor
Security Guards
M.D.
Parttime (Consultant) Psych.
Financial Manager (Comptroller)
AIDS Coordinator (s)

Research Director (1)
Research Assistant (2)
Quality Assurance Person

Community Liaison & Outreach Workers (1-2)

VI. EVALUATION: (Once Yearly)
- Done by Research Director (OMT)
and Quality Assurance Person (ongoing)
(Manage charts/records)(Reports)

VII. Funding Sources - Suggestions

C.W.A.
Ford Foundation
DSAS
NIDA

CONCLUSIONS:

1. Completed proposal by mid-March

2. Next Meeting, WEDNESDAY, FEBRUARY 14, AT 9: A.M.

T. Campbell Officiated

3. ASSIGNMENTS:

Research - Funding sources - W. Walsh & Dr. John
Proposal Writing - E. Callendar & G. Frost-Meredith.

OUTLINE FOR SPECIAL PROJECT

Sub-Committee Members

G. Frost-Meredith
E. Walsh
Dr. B. John
E. Callender
T. Campbell

Name of Center: Comprehensive Family Services Center

Sites: Two separate sites serving:
1. Mary Immaculate - Queens
2. St. Mary's - Brooklyn

Brooklyn Site: Central, offering easy access to patients from Addiction Services clinics.

- Possible area - Bed-Stuy
- Committee members will begin search to locate available building. Will solicit help of Archdiocese of Brooklyn.
- Recommendation - purchase of building as opposed to renting.
- Site/building specifications to be rewritten into proposal.

Target Population:
25 families at each site comprising:

1. Contractual referrals (funding sources)
2. Referrals within methadone clinics.
3. Other agency referrals (to include Community Boards).

Hours of Operation:
Center will operate 6-day schedule - Monday thru Saturday.
M-F between the hours of 7:00 a.m. and 9:00 p.m.
Saturday - limited hours based on activities.

Services: Center will offer a variety of family services, comprising the following components:

1. Family Services

   Consisting of therapeutic/support services:

   a. Individual, family, group therapy, targeted to specific needs of individual family.

2. Educational/Recreational Services - Two components

   A. Speaker's Bureau
      - lecturing
      - workshops
      - presentations inside and outside of site
      - vocational services

   B. Prevention Services including HIV/Risk Reduction
      - Involvement with school based programs e.g. "SPARK"
      - Prevention education
      - Pre-post test counseling for HIV.

   C. Recreational Activities

3. Expansion of Current Addiction Services Programs

   - Special program for crack/cocaine abusers
   - After-care, support and transitional groups
   - AA meetings, NA, CA

4. Community Outreach
   - Health Fairs
   - Networking
   - Community Newsletter
   - Involvement with community groups

5. Special Research Component
   A. Institutional research
      - evaluate outcome
      - Point direction
      - Quality Assurance
      - Annual reports

   B. Developmental Research
   - Generate funds
   - Explore needs and potential funding sources
   - Maintain funding

C. Creative Research
  - Look at problem areas
  - Look at transitional/longitudinal problems
  - Generate new ideas
  - Do follow-up studies

6. FUNDING SOURCES

Identification of funding sources to be done through library search.

Possibilities

- CWA
- Dept. of Health
- NDA
- Ford Foundation

(Ms. Meredith and Mr. Walsh to do research in this area).

ADDENDUM NUMBER 2 TO WRITTEN TESTIMONY
PRESENTED TO THE SELECT COMMITTEE

SUBMITTED MARCH 27, 1990

Robert G. Newman, M.D.

BETH ISRAEL MEDICAL CENTER FIRST AVENUE AT 16TH STREET, NEW YORK, NY 10003 (212) 420-2873

Robert G. Newman, M.D.
PRESIDENT

March 27, 1990

Honorable C. B. Rangel
Adam C. Powell Jr.
State Office Building
153 West 125th Street
New York, N.Y. 10027

Dear Congressman Rangel:

As promised at Friday morning's Hearing of the Select Committee, I enclose a copy of the relevant section* of the methadone maintenance treatment program contract between Beth Israel Medical Center and the New York State Division of Substance Abuse Services. The bottom line is that the contract precludes absolutely any "profit" from the operation of the program. If the total revenues from the State contract, Medicaid, self-pay patients, and from any other sources should exceed expenditures, the entire excess must be returned to the State.

Let me also stress again that the so-called "Medicaid mills," which I too view with the greatest dismay, are not in any way analogous to public methadone treatment programs. Speaking for Beth Israel, I can state unequivocally that not a single person associated with our program - administrators, physicians, nurses, counselors, social workers, etc. - receives compensation which is determined by the program's enrollment, the number of visits, or the frequency or type of services provided. I believe the same applies to all other programs supported by the State.

With best wishes,

Sincerely yours,

Robert G. Newman, M.D.

Robert G. Newman, M.D.

cc: Mr. Arthur Webb

* Underlined in text agreement that follows.

AFFILIATED WITH MOUNT SINAI SCHOOL OF MEDICINE MEMBER OF UJA-FEDERATION OF JEWISH PHILANTHROPIES

STATE OF NEW YORK
DIVISION OF SUBSTANCE ABUSE SERVICES
EXECUTIVE PARK SOUTH, BOX 8200
ALBANY, NEW YORK 12203

JULIO A. MARTINEZ
Director

January 31, 1989

NINA P. PEYSER
ASSISTANT DIRECTOR, OPERATIONS
FEB - 2 1989
BETH ISRAEL MEDICAL CENTER
RECEIVED

Ms. Nina Peyser
Administrator
Beth Israel Medical Center
10 Nathan D. Perlman Place
New York, New York 10003

Dear Ms. Peyser:

Enclosed please find one fully executed and approved copy of Contract C-002413 between this Division and Beth Israel Medical Center for the operation of a substance abuse program. The enclosed agreement covers the period October 1, 1988 through September 30, 1989 in the maximum reimbursable amount of $7,949,388.

If you have any questions or require assistance, please contact your regional contract manager.

Sincerely,

Joseph Marshall

Joseph T. Marshall
Bureau of Contract Management
and Fund Allocation

Enclosure

cc: Regional Office #7C, w/enclosure

AGREEMENT

WHEREAS, the Division is empowered to enter into agreements with governmental agencies, non-profit corporations and other entities for the provision of substance abuse services within the amounts made available by appropriation; and

WHEREAS, the Contractor certifies that it and each of its subcontractors, if any, have secured all necessary approvals, licenses and/or permits from Federal, State and other authorities that may be required for the operation of the program; and

WHEREAS, the Contractor represents that it is ready, willing and able to conduct the program contemplated by this agreement.

NOW, THEREFORE, in consideration of the foregoing, and of the mutual covenants herein, it is agreed as follows:

1. Period of Performance

Notwithstanding the date of execution, the period of this agreement shall be deemed to commence and to terminate as of the effective date and expiration date stated on the face page.

2. Statement of Work

(a) The Contractor shall conduct, either directly or through subcontracts approved by the Division, a substance abuse services program (hereinafter: "program"). The program shall be performed in accordance with the detailed workscope approved by the Division, and in conformity with any required Comprehensive Plan. The Contractor agrees that it will conduct the program in full compliance with all applicable Federal and State laws, rules and regulations, in addition to any and all applicable guidelines or other directives issued by the Division pursuant to administrative bulletins, policy and procedure manuals or otherwise.

(b) The Contractor agrees to conduct the program in a competent, skillful and professional manner and to the best of its ability. It is agreed that the nature and extent of the services provided pursuant to this agreement shall be under the professional jurisdiction of the Contractor, subject, however, to such evaluative or supervisory responsibilities as are assigned by law to the Division.

3. Consideration and Other Program Income

(a) As consideration for the performance of this agreement, the Division agrees to pay, and the Contractor agrees to accept as payment in full, and in complete discharge of the Division's obligation, reimbursement for the approved costs incurred by the Contractor in the conduct of the program pursuant to this agreement. In no event shall the total obligation of the Division exceed the Maximum Reimbursable Amount stated on the face page, subject to the maximum amounts indicated for the categories specified in the Contract Matrix Summary attached and made part of this agreement, and the approved budget. The Contractor agrees that it shall conform to the terms of the Contract Matrix Summary and approved budget, and to all applicable provisions of the Federal, State and Local Laws, and customary prevailing governmental practices and standards.

(b) In the event that the program of the Contractor includes activities to be conducted through subcontracts with other public or private agencies or other separately identified program activities, the parties understand that the Maximum Reimbursable Amount specified as the monetary consideration for this agreement includes the particular amounts intended for each subcontractor, but only to the extent that the same are set forth in separate schedules, which shall be attached and made part of the agreement. It is further understood and agreed to by the parties that grants pursuant to this agreement for any subcontractor set forth in such schedules shall not be payable unless the Contractor submits, when requested by the Division, evaluative and such other data with respect to each subcontractor in the manner and form as shall be required by the Division.

(c)(i) Any inconsistent provision of "Art. C" of this agreement notwithstanding, any fees paid by or on behalf of a recipient of services for such services, and any money contribution of such recipient to the Contractor or to any subcontractor for services and activities conducted in implementing the program shall be accounted for and applied in such manner and to such purpose as shall be provided by the approved budget for the program.

(ii) Any income derived from any funds provided by the Division pursuant to this agreement shall be accounted for and applied in such manner and to such purpose as shall be provided by the approved budget for the program.

(iii) With respect to outpatient methadone maintenance treatment programs, any source of support, including local tax levy monies, other than Division reimbursement, shall be applied in reduction of each monthly application for reimbursement in the month in which those other funds are received. The balance of total costs, shall then be subject to reimbursement by the Division but in no event in an amount in excess of the Maximum Reimbursable Amount stated on the face page.

(iv) Unless otherwise directed by the Division, the Contractor shall submit to the Division a monthly statement of expenditures as well as a revenue statement on forms to be supplied by the Division. It is expressly understood by the parties that the local share of public assistance payments is not to be considered as part of local tax levy or other locally appropriated funds committed to the program.

(v) Nothing herein shall serve to increase the Maximum Reimbursable Amount. The Contractor agrees that in no event shall Federal funds provided by the Division or State aid be used to substitute for or supplant other available funds.

(d) Any revenue received by the Contractor or subcontractor during the term of this agreement, shall first be applied toward the total costs incurred in the performance of the program. The balance of such total costs remaining, shall then be subject to reimbursement from the Division.

(e) The Contractor and its subcontractors, if any, shall refer patients clearly or potentially eligible for third party payments, as soon as practicable after acceptance of such patients into the program, to the appropriate third party payor for a determination of their eligibility for such payment. In the event that the Contractor or any of its subcontractors fails, refrains or omits to pursue all sources of revenue to which the program, its services or its clients are entitled, then the Division shall have the right to deduct from the costs eligible for reimbursement, an amount equal to the amount of such sources of revenue that should have been collected.

(f) The Budget submitted by the Contractor, and approved by the Division, may be amended only with specific Division approval. All requests for budget amendments must be on forms supplied by the Division.

(g) The parties further understand that any and all amounts specified in this instrument are subject to the provisions of "Art. N" of this agreement and that they represent the amounts which could be available if the Legislature makes appropriations in the amounts requested by the Governor or otherwise for this purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Alcohol, Drug Abuse and
Mental Health Administration
Rockville MD 20857

For Release Only Upon Delivery

STATEMENT
BY
CHARLES R. SCHUSTER, Ph.D.
DIRECTOR
NATIONAL INSTITUTE ON DRUG ABUSE

BEFORE

SELECT COMMITTEE ON
NARCOTICS ABUSE AND CONTROL
U.S. HOUSE OF REPRESENTATIVES
ON
THE EFFECTIVENESS OF METHADONE TREATMENT

9:30 A.M.
FRIDAY, MARCH 23, 1990
U.S. COURT OF INTERNATIONAL TRADE
CEREMONIAL COURTROOM, 1 FEDERAL PLAZA
NEW YORK, NEW YORK

Mr.Chairman and Members of the Select Committee. I am Charles R. Schuster, Director of the National Institute on Drug Abuse (NIDA) of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). I appreciate having this opportunity to discuss what is known about the effectiveness of methadone treatment.

Although methadone is still considered a controversial treatment, it has been used successfully in treatment of drug abuse for over 20 years. I think it is useful and necessary to review what we have learned about methadone during those years.

Background

Methadone is a legal, orally-administered synthetic opiate that can be used for the treatment of heroin and other opiates that are typically injected intravenously. Perhaps no other treatment for opioid addiction has been studied as extensively as methadone maintenance. Longitudinal studies of opioid users in treatment have consistently shown that methadone maintenance treatment has better rates of retention and outcomes that are equal to or more favorable than other modalities. Long-term methadone treatment is accepted by a high proportion of heroin addicts, with voluntary retention rates of two years or more ranging from 55 percent to 85 percent in different clinics. Approximately 74,000 addicts are in methadone treatment at any one time. Methadone treatment programs typically operate on an outpatient basis, require medical supervision, and provide both counseling and some general medical care. When administered on a daily basis, methadone allows the addict to function normally without fear of opiate withdrawal symptoms. Most importantly, it eliminates the need to inject heroin intravenously.

Current Research on Methadone Treatment of Opioid Dependence

It has been known since the late 1960s (Dole and Nyswander) that heroin addicts experience immediate and dramatic reductions in drug use following enrollment in methadone treatment, and that these reductions continue throughout treatment. Since then, numerous studies have illustrated these reductions, with an average of 75 percent of clients using no illicit opiates while in long-term quality treatment. A large-scale study of 44,000 addicts enrolled in 52 treatment programs found that opiate use by clients in methadone treatment was reduced from an average of 30 days per month to 1 to 2 days per month. The longer addicts remain in methadone treatment, the more effective it is in reducing illicit opiate use. In one recent study, opiate drug use decreased from 100 percent of addicts entering treatment to 23 percent of those in treatment for 1 to 4 years and 8 percent of those in treatment for 5 or more years.

Evidence suggests that long-term maintenance of addicts on methadone allows the normalization of many facets of human physiology that have been altered by heroin use. Although the addict remains physiologically dependent on an opiate drug, the preoccupation with obtaining heroin each day is removed. This, in turn, facilitates the normalization of behavior with resulting improvements in the reduction of illicit drug use, criminal activity, employment, and social functioning. This takes longer for some individuals than others. In some cases addicts can be gradually withdrawn from methadone after several months to lead drug-free lives. More typically, addicts must be maintained on methadone for longer periods, with some requiring prolonged treatment. Indeed, some addicts have been maintained on methadone for 10 years or longer. There is no evidence that long-term methadone maintenance has adverse medical consequences, and it continues to be effective in reducing heroin use while it is administered.

In methadone treatment, outcome success depends in large part on the ability of the program to retain clients until they have satisfactorily completed treatment. Satisfactory treatment outcomes for these clients is also contingent on the availability of programs to provide a full range of counseling, vocational, rehabilitation and treatment services, especially to those individuals diagnosed with coexisting alcohol, drug, and/or mental health conditions.

Most clients who drop out of treatment prematurely eventually relapse to opiate use. However, rates of abstinence are high for those patients who satisfactorily complete treatment. For example, in a study that followed heroin addicts for as long as 6 years after methadone treatment (Stimmel _et al._, 1977), 83 percent of those who terminated with staff approval were opiate-free, compared to only 18 and 13 percent, respectively, who terminated prematurely or were arrested.

Quite recently, NIDA-supported research has provided an updated picture of methadone treatment. This work found that some 71 percent of addicts who stayed in treatment on a prolonged basis stopped intravenous drug use, and about one third of patients who completed the full treatment course remained abstinent. Short-term drop out from treatment led to relapse to intravenous drug use in the majority of cases. The investigators (Ball _et al._, 1988) also found wide variability in the quality and efficacy of the methadone programs in the study. Some achieved cessation of intravenous drug use in only about 40 percent of their clients, while other programs achieved up to 90 percent abstinence.

Finally, it is clear that methadone maintenance can significantly reduce the transmission of AIDS among intravenous drug abusers. By reducing intravenous drug use, methadone maintenance is effective in reducing the sharing of contaminated needles. Indeed, one study in the New York area has reported markedly lower rates of seropositivity among heroin addicts in methadone maintenance programs (23 percent) than heroin addicts not in treatment (47 percent). Other studies have reported significantly lower seropositivity rates for addicts enrolled in methadone maintenance programs for several years than for addicts recently admitted to treatment programs.

Current Activities and Future Directions

Recognizing the importance of reducing the spread of HIV infection, in March 1989, the Food and Drug Administration (FDA) and NIDA proposed to revise the Federal regulation to provide a new treatment modality called "Interim Methadone Maintenance Treatment." This initiative was proposed in response to the AIDS epidemic in the intravenous drug abusing population. It is intended to help reduce the spread of HIV infection within this population by providing temporary treatment at existing methadone treatment programs until comprehensive treatment is available. The FDA convened a public hearing on the issue given the diverse responses to the proposal. They are now consolidating and reviewing comments.

Methadone is a very effective medication for the treatment of opiate addiction. I pointedly use the word "medication" rather than "drug." We have been unduly burdened by the fact that we do not have different words to refer to chemicals used for treatment as opposed to those being abused. Unfortunately, semantics sometimes get in the way of reality and there are those who say you should not use drugs to treat drug abuse. Nothing, of course, could be further from the truth.

However, there is some negative public feeling against the use of methadone, so we are trying to develop alternative medications which we hope will improve the acceptability of agonist (replacement) therapy. We are renewing our efforts to develop LAAM (a long-acting replacement drug with limited abuse potential) and are seeking a contractor to evaluate the existing data and determine what more has to be done so it can reach the marketplace.

Of perhaps greater interest is buprenorphine, a medication providing both agonist and antagonist (blocker) effects in a single dosage form, which is being actively studied both by extramural scientists and at NIDA's own Addiction Research Center. For those patients who are opiate-free but require "protection" against readdiction, NIDA developed in partnership with DuPont, the narcotic antagonist naltrexone, which in effect immunizes against narcotic addiction. While naltrexone appears to be an ideal medication in many ways, there have been significant problems with patient compliance. We are, therefore, developing a "depot" form of this medication, which is slowly released over time. We believe this may provide a powerful public health tool in the 90s. Lastly we are seeing some hopeful signs in regard to cocaine addiction treatment.

Currently, there are only two medications - methadone and naltrexone, specifically approved for the treatment of opiate addiction. Nothing is available for cocaine. We know that medications work in the treatment of drug addiction when used appropriately. There is a desperate need to increase our treatment capacity and effectiveness, and medications will help us do this. Advances in drug abuse research over the past decade, and especially over the last five years, have led the field to a point where there are many sound scientific reasons for pursuing the development of many types of medications. The AIDS epidemic adds a new urgency to the search for effective treatment for drug abuse.

NIDA's new Medications Development Program includes activities designed to both discover new pharmacological therapies for treating drug addiction and to bring these therapies to market. In NIDA, we are also pursuing research to develop a range of other effective therapies including adjunctive therapies to be used with medications, psychosocial treatment of drug abuse, rehabilitative services, linkages to social services, the criminal justice system, and education/job training programs.

Future directions for methadone research encompass a variety of areas, including:

- Studies of methadone maintenance programs in comparison to other types of medical outpatient chronic care;
- Development of research instruments to describe and quantify the components of methadone maintenance programs;
- Studies of optimal dosing, prescribing, and dispensing policies and procedures; and
- Comparative studies of the relative treatment value and cost effectiveness of services beyond the simple dispensing of methadone.

In addition to the research discussed above, NIDA is currently engaged in a feasibility study designed to improve methadone treatment. Managers at all levels need to be able to identify strengths and weaknesses of methadone treatment programs and identify areas in need of improvement. In October, 1989, NIDA awarded a 2-year contract to the Research Triangle Institute (RTI) in collaboration with the National Association of State Alcohol and Drug Abuse Directors (NASADAD). The objective of the project is to study the feasibility of establishing a performance-oriented Methadone Treatment Quality Assurance System (MTQAS) to monitor and aid in improving the quality and effectiveness of treatment provided by registered methadone treatment programs.

The system will be a performance-based process capable of identifying and categorizing methadone treatment programs by the addiction severity of patients served and other appropriate program and patient characteristics and in terms of the outcomes achieved by their patients during treatment.

Conclusion

Methadone is certainly not a cure for heroin addiction. It must be administered daily. It maintains physical dependence on opiates. Nevertheless, methadone is a successful treatment of heroin addiction and a valuable tool for preventing the spread of AIDS. The concept of methadone maintenance is consistent with the medical management and treatment (not cure) of a number of other diseases, including diabetes, heart disease, and arthritis.

Mr. Chairman, we have a common mission, a common passion, which is to stop the ravages of drug abuse in our people. We believe that methadone maintenance has a place in the treatment of heroin addiction. The 25 year old heroin addict who comes into the clinic and is placed on methadone is no longer an addict. That person is physically dependent on opiates, but not addicted to them. This is an essential and not semantic distinction. Methadone stabilizes brain dysfunction caused by years of heroin addiction, and stops the on-off cycling that typifies addiction. This person no longer injects drugs, is no longer constantly involved in drug-seeking behavior, and can be gainfully employed and involved in rehabilitation programs. This person no longer needs to commit crime to support his or her drug addiction. Perhaps most importantly, the risk of contracting AIDS and/or transmitting it to someone else is substantially reduced.

Mr. Chairman, I am pleased that you are focusing attention on methadone diversion. I would support full implementation of existing controls and penalties of the Controlled Substances Act for all persons found illegally distributing methadone, as with any other Schedule II substance. That such persons are also enrolled in a methadone program should be not exempt them from full prosecution under Federal and State statute. This action is the only reasonable method for sharply curtailing methadone diversion. While some of our colleagues might argue that eliminating all methadone take-home privileges would decrease diversion, such action would severely jeopardize the rehabilitation process of thousands of responsible, productive patients struggling to recover from this pernicious disease.

Methadone was the first medication available for the treatment of heroin addiction. We need to continue its use until it is replaced by something better. I'd be happy to answer any questions the Committee might have.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

OF

STUART L. NIGHTINGALE, M.D.

ASSOCIATE COMMISSIONER

FOR HEALTH AFFAIRS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL

U.S. HOUSE OF REPRESENTATIVES

U.S.COURT OF INTERNATIONAL TRADE
CEREMONIAL COURT ROOM
1 FEDERAL PLAZA
NEW YORK, NEW YORK

March 23, 1990

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman and Members of the Committee:

I am Stuart Nightingale, M.D., Associate Commissioner for Health Affairs, Food and Drug Administration (FDA). I am accompanied by Ross Laderman, who is Deputy Director of the Division of Scientific Investigations, Center for Drug Evaluation and Research, and George Prager, who is an investigator, in FDA's New York District office. We are here in response to your request to the Department of Health and Human Services (HHS) to testify on the regulation of methadone maintenance as a treatment modality and, especially, the status of our joint FDA/NIDA methadone interim maintenance proposal.

BACKGROUND

As you know, FDA shares responsibility with the National Institute on Drug Abuse (NIDA) and the Drug Enforcement Administration (DEA) for regulating the use of methadone in narcotic addiction treatment programs. Methadone is a synthetic narcotic drug approved as an analgesic and for use in the treatment and detoxification of narcotic addicts. Regulations, developed under authority of the Narcotic Addict Treatment Act of 1974 and the Federal Food, Drug, and Cosmetic Act detail the minimum requirements for using methadone in maintenance and detoxification treatment. These regulations require that methadone maintenance treatment programs provide comprehensive social services (counseling, treatment plans, vocational rehabilitation, etc.) in addition to providing medical services and dispensing methadone. FDA is responsible for ensuring that all programs using methadone are in compliance with FDA/NIDA treatment regulations for maintenance and detoxification. Other authorities, including DEA, and individual State authorities also apply requirements (including pre-approval requirements) for methadone treatment programs.

Methadone has been used for over 20 years to treat narcotic addiction. More than 900 inpatient and outpatient methadone treatment programs are approved and are currently operating. FDA, with the concurrence of DEA and NIDA, has approved approximately 695 methadone maintenance treatment programs in 45 States, the District of Columbia, the Commonwealth of Puerto Rico, and two territories. In addition, 283 hospital inpatient detoxification treatment programs have been approved nationwide. Four states have no approved methadone treatment programs.

Methadone Program Regulatory Compliance

During the period of the early and mid-1980's, methadone compliance inspections were considered less of a priority and the Agency limited inspections to "for cause" situations, with severe compliance problems. Most of the inspections during this period were carried out by State authorities.

Recently, however, FDA has redesigned its program to routinely perform surveillance compliance inspections of methadone treatment programs to ensure compliance with the methadone regulations. This new program is due in part to the Anti-Drug Abuse Act of 1988, which authorized $5 million to be used to expand FDA's drug abuse activities (those relating to counterfeits, methadone, and anabolic steroids). As a result, approximately 21 FTE's were allocated to the FDA field offices with a considerable portion to be used to conduct additional methadone treatment program inspections. FDA projected 498 inspections for FY-90. This is consistent with the Agency's desire to inspect one-half of the existing methadone treatment programs each fiscal year. Approximately 19 percent of these projected inspections have been conducted, resulting in 77 field recommendations for follow-up actions. These 77 actions are comprised of 8 regulatory letters and 69 notices of adverse findings. At present, the Agency plans to conduct biennial surveillance inspections of all narcotic treatment programs. The inspection and follow-up process are described below.

Compliance Inspection Process

The FDA Compliance Program Guidance Manual (7348.002, Methadone Programs) contains the policy and procedures for FDA monitoring of narcotic treatment programs to determine if the practices of these programs comply with current regulations. Among other things, this compliance program directs our field investigators to examine records of the most recently admitted patients, generally those admitted in the six months preceding initiation of the inspection. This is because many of the most critical aspects of the regulations relate to patients entering treatment - e.g. do the records show that a program physician determined the patient's current physiologic dependence and history of at least one year's physiologic dependence addiction as required before admittance to treatment?

When FDA field staff believe that follow-up action is required as a result of an inspection it forwards its recommendation to headquarters that either a Regulatory Letter, the letter used for most severe problems, or a Notice of Adverse Findings, the letter for less severe problems, be issued to the sponsor of the program. At headquarters, the Division of Scientific

Investigations (DSI) reviews the field recommendation for concurrence or determination of alternative actions. Upon DSI concurrence, the District Office notifies the sponsor, by letter, of FDA's intention. In the case of a Notice of Adverse Findings (the lesser of the two sanctions) the sponsor is offered 30 days to respond, describing corrective actions taken to bring the program into compliance with FDA regulations; an unannounced reinspection within 6 to 12 months is scheduled to verify corrective actions.

In the case of a Regulatory Letter, a more severe action based on significant violations and/or a history of violations without corrective action, the sponsor has ten days after receipt to explain its position in an informal conference at the District office and/or in writing. If the information presented at the informal conference or in written response does not show that the program's operations are tentatively acceptable, the District office may draft a letter for issuance by the District Director to the Drug Enforcement Administration requesting that the Administrator suspend or revoke registration for non-conformance with HHS standards. This is the typical ultimate sanction as a result of a program's noncompliance, and is expected to result in the DEA Administrator's initiating proceedings to revoke or suspend the program's registration under the Controlled Substances Act

(CSA). Such a recommendation for suspension or revocation would be based on non-conformity with HHS standards. Although a much more lengthy and burdensome regulatory process than the CSA route described above, the methadone regulations allow for FDA itself to revoke a methadone program's approval.

If a registrant presents information in writing or in an informal conference that the conditions observed by FDA in its Regulatory letter have been or will be satisfactory, the District will reschedule an unannounced follow-up inspection to verify such statements. If the findings of the follow-up inspection do not show that there is appreciable correction of the conditions consistent with the applicant's response, the District Director, upon DSI concurrence, requests that the DEA revoke or suspend the applicants registration. However, the regulations provide for immediate suspension of approval and expedited subsequent administrative procedures if the Secretary of Health and Human Services determines that there is an imminent hazard to health.

When conditions requiring suspension or revocation of the registration have been corrected, the District office will recommend that DEA "remove the code" thereby allowing automatic annual DEA program re-registration.

Interagency Cooperation

At the federal level, interagency cooperation and coordination in conducting these inspections and in evaluating their results for follow-up actions are not only encouraged, but are institutionalized in program guidances, memoranda of understanding (one each with DEA and NIDA), and interagency agreements. In addition, the Methadone Treatment Policy Review Board met regularly in the 1970's as methadone programs grew in number and has continued to meet periodically since the late 1970's to address interagency (FDA, DEA, NIDA) policy concerns. Similarly, the Interagency Committee on Drug Control (FDA, DEA, NIDA, Office of the Assistant Secretary for Health) meets monthly and occasionally considers methadone policy issues. These coordination and cooperation procedures also apply to FDA-State interactions in regulating methadone treatment programs. Indeed, FDA regulations require State approval before a program can be approved by FDA. Additionally, a number of States carry out their own inspections.

Diversion

The potential for diversion of methadone by patients has been a concern since the inception of methadone maintenance programs that provide take-home methadone. FDA is acutely aware of diversion issues and problems surrounding methadone treatment programs, including the problems identified in the New York Post article cited in the Committee's letter of invitation. The Agency, along with counterpart agencies, is prepared to act quickly and to address thoroughly such problems. Indeed, after receipt of a similar series of articles published in Newsday in 1989, FDA, DEA and representatives from the State conducted five joint inspections in August 1989. All of the programs inspected were notified of violations by letters. FDA met with one of the programs directly, to require it to explain its plan to correct the deficiencies cited.

The issue of diversion is the subject of interagency discussions among FDA, NIDA, and DEA at ongoing fora such as the Interagency Committee for Drug Control, the Methadone Policy Review Board, and, on an ad hoc basis, when a particular problem is identified, directly with the treatment program.

Effectiveness of Methadone Treatment

It is important to point out that FDA/NIDA methadone regulations promulgated under the Narcotic Addict Treatment Act are "minimum standards" that provide a legal framework to allow the medical administration of narcotic drugs (such as methadone) to narcotic addicts to treat addiction.

While the regulations foster quality in programs, there are a number of intangibles such as compassion, communication, insight, neighborhood support and other elements of a good program that cannot be established by regulation. Moreover, concrete factors such as funding, other support services and resources, etc., are also important parts of a good program, although not part of the regulatory approach. Nonetheless, we do believe that the frequency of inspections is an important element not only assuring compliance with the regulations, but in improving the quality of programs beyond the written requirements.

Inasmuch as FDA's role in improving the quality and effectiveness of methadone treatment programs is limited by regulatory and statutory constraints, the Agency acknowledges and encourages measures on the part of others that can contribute to the quality and effectiveness of programs. Results from research funded by NIDA indicate that there are consistent techniques employed by "successful" methadone programs. Many of these techniques were identified in a recently conducted study by John Ball, Ph.D. Importantly, FDA recognizes the efforts by NIDA to obtain systematic data to evaluate all types of drug abuse treatment programs, such as the **Uniform Program and Performance Reporting** system. Moreover, FDA joined NIDA in proposing the **Methadone Treatment Quality Assurance System** (MTQAS) which was announced in the March 2, 1989, Federal Register. As proposed under MTQAS, NIDA would periodically compile and publish the aggregate results of urine tests and retention rates. These rates, adjusted for client severity, would serve as a benchmark against which programs can compare themselves, and States can make licensing, inspection, and funding decisions.

Prior to initiating the plan to increase methadone treatment program inspections discussed above, FDA conducted a two-day training session for FDA investigators. Representatives from NIDA, DEA, and FDA made formal presentations describing among other topics, how the regulations apply to treatment quality.

In addition to its role in regulating methadone treatment programs, FDA has responsibilities in other drug abuse treatment areas. As stated earlier, FDA approved the use of methadone to treat narcotic addiction after it had been used for many years only as an analgesic. The Agency has special review divisions, procedures, and interagency agreements to expedite the review and evaluation of new medications to treat drug abuse.

Interim Maintenance Proposal

Under the March 2, 1989, Interim Maintenance proposal, methadone would be dispensed on a temporary basis without the scope of comprehensive support services (counseling, vocational rehabilitation, etc.) required in traditional comprehensive programs. The proposal was viewed as a public health measure. It was based on the fact that there is a high rate of HIV infection and transmission among IV drug abusers amid reports of widespread treatment shortages in certain areas of the country -- with long waiting lists to enter methadone treatment. Measures, such as interim maintenance, were recommended in the report of the Presidential Commission on the HIV Epidemic, as temporary bridges until comprehensive treatment capacity could be expanded. Beth Israel Medical Center had established an approach under an Investigational New Drug application for treating narcotic addicts in such a "holding program" while awaiting comprehensive treatment.

FDA and NIDA received over 80 comments in response to the March 1989 proposal. Some commenters suggested a public hearing or meeting to address their concerns about the proposal, and, on February 28, 1990, FDA and NIDA convened a public hearing. Twenty-three individuals or organizations testified at this public hearing. The Federal Register notice announcing the hearing detailed the issues and areas of concern identified in the comments to the proposal, and asked that data and evidence be presented that would address these topics. These issues included the nature and extent of waiting lists, the potential impact of interim maintenance on comprehensive methadone treatment, elements of a policy for transferring patients from interim maintenance to comprehensive treatment, poly-drug abuse, and urine testing.

In announcing the hearing, FDA and NIDA requested data and evidence on the impact of interim maintenance on treatment quality and diversion; two of the topics identified in your invitation letter. The Agencies anticipated that by proposing to allow no take-home privileges for patients in interim maintenance that diversion of methadone by this avenue would be virtually non-existent.

A wide range of information and evidence was presented during the hearing both in support of and against the proposal. The administrative record for the hearing has only recently closed (March 15, 1990), and the Agencies are presently consolidating and reviewing the comments received.

FDA and NIDA hoped that the data and evidence presented during the hearing would help to resolve concerns raised about the interim maintenance proposal and allow agencies to take a definitive step in one direction or the other.

Thank you, Mr. Chairman, that concludes my formal testimony. My colleagues and I will be glad to answer any questions you may have.